

Exhibit 2

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SUPPLY AGREEMENT

This Agreement (the "Agreement") is made as of the 15th day of April 2001, by and between Johnson & Johnson Consumer Companies, Inc. ("Buyer"), and Luzenac America, Inc. ("Seller").

WHEREAS, Seller is in the business of making the product described in Annex A to the Agreement (the "Products") and Buyer would like to purchase Products from Seller pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties hereto agree as follows:

1. Purchase and Sale of Products.

- (a) During the term of this Agreement, Seller shall supply Buyer with those quantities of Products as ordered by Buyer pursuant to this Agreement and Buyer shall purchase from Seller 100% of Buyer's requirements for Products containing cosmetic grade talc to be manufactured in Royston, Georgia. Nothing set forth in this Agreement shall obligate Buyer to purchase any specific minimum quantity of Products from Seller.
- (b) The Products shall conform to, and shall be manufactured in accordance with, the specifications as set forth in Annex A attached to this Agreement, and as the same may subsequently be mutually agreed to in writing by the parties hereto or prescribed by any local, state or federal regulatory agency (collectively, the "Product Specifications"). From time to time during the term of this Agreement, either party may submit written proposals for the adoption or development of improvements relating to the Products. If the parties mutually determine to pursue such improvements they shall mutually agree upon modifications to the Product Specifications to reflect such improvements as well as revisions to the price to be charged for the Products.
- (c) The initial price for Products ordered by Buyer during the first twelve months of this Agreement shall be as set forth in Annex B attached to this Agreement. On April 15, 2002 and April 15, 2003, the price for Products prevailing during the Contract Year (as such term is defined in Section 22 (b) below) just ended shall be increased or decreased for the Contract Year commencing on such dates in accordance with the proportionate increase or decrease in the Producer Price Index for Nonmetallic Mineral Products, Minerals and earths ground or treated, Series ID PCU3295#1 (the "Index"), published by the United States Department of Labor, Bureau of Labor Statistics (the "BLS"). In the event that this series

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is no longer published or is otherwise unavailable, then Series ID PCU3295# shall be used. The proportionate increase or decrease in the Index shall be determined by comparing the average of the final or preliminary Index data for the most recent January, February and March obtained from the BLS website during the second week of April to the average of the final Index data for January, February and March of the year prior to the Contract Year just ended. Index data used for the purposes of this Section 1(c) shall not be seasonally adjusted. For greater certainty, but by way of illustration only, a sample calculation for adjustment of the purchase price is set forth in Annex B attached to this agreement.

- (d) The prices charged by Seller to Buyer as set forth in Annex B, or as may subsequently be determined, shall include all costs for F.O.B. Ludlow, Vermont (the "Shipping Point"). The risk of loss with respect to Products shall pass to Buyer upon notification to Seller by Buyer of acceptable microbiological testing results from Product samples obtained during railcar loading, and Seller's release of said railcar to the rail carrier.
- (e) In addition to any price increases or decreases determined pursuant to this Agreement, Seller shall actively investigate and present to Buyer, cost savings opportunities having the potential to reduce either prices charged by Seller to Buyer or Buyer's processing costs by 4% per year. Nothing set forth herein shall obligate either party to implement any cost savings opportunity presented to Buyer.

2. Forecasts; Orders.

- (a) Buyer shall provide Seller electronic access to a non-binding forecast of Buyer's expected requirements for Products during the following quarter. Buyer shall place binding orders for Products by written or electronic purchase order (or by any means agreed to by the parties) to Seller, which shall be placed at least 18 calendar days prior to the desired date of shipment.
- (b) To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance of any similar document, the terms of this Agreement shall govern.

3. Shipment; Inventory; Invoices; Payment.

- (a) All charges for packing, hauling, storage, bar coding, transportation to and loading at the Shipping Point are included in the purchase price unless otherwise agreed to by the parties. All shipments must

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be accompanied by a packing slip which describes the Products, states the item number, purchase order number and shows the shipment's destination.

- (b) Seller shall invoice Buyer within 48 hours following shipment of Products to Buyer. Buyer shall pay Seller the purchase price set forth on such invoices not later than thirty (30) calendar days following the date of Seller's invoice.
- (c) Seller will maintain inventory of Products on a first-in, first-out basis. At all times during the term of this Agreement, Seller shall maintain an adequate number of dedicated silos to ensure timely shipment of all Products ordered by Buyer hereunder. Seller and Buyer agree to cooperate to improve the process for ordering Products with the mutual objectives of expediting the supply process to a Lean Supply process and reducing inventory costs.
- (d) In the event that Seller shall be unable or unwilling or shall fail to supply such Products in such quantities as Buyer shall request and in compliance with the shipping periods set forth herein or as otherwise requested by Buyer (other than as a result of a force majeure event as described in Section 9), then Buyer shall be permitted (with no obligation or liability to Seller) to obtain Products from another source and such inability, unwillingness or failure to supply Products shall be deemed a material breach of this Agreement, *provided, however*, that Seller shall have no liability to Buyer in the event that Buyer shall fail to make sufficient railcars available to Seller for loading of any order or any portion thereof.

4. Product Acceptance; Corrective Actions; Assistance.

- (a) Shipment of Products by Seller to Buyer shall constitute a certification by Seller that Products have been tested, and been found to conform fully to the Product Specifications and are free from defects. In the event that Buyer conducts testing on the Products for non-microbiological parameters, Buyer shall forward the results of such tests to Seller as soon as possible. In the event of dispute between the parties concerning conformance to any of Buyer's non-microbiological specifications as described in Annex A, Buyer shall give written notice of such dispute to Seller as soon as possible. Immediately after such notice, each party shall submit a sample of the Product to a mutually satisfactory third party laboratory. Seller shall also submit to the laboratory a third untested, sealed portion of Product sample. Such laboratory shall determine, in its judgment, whether the shipment conforms with the Product Specifications as evidenced by the Product sample. The decision of the third party laboratory shall be final, and all costs and

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expenses pertaining to such testing by the third party laboratory shall be shared equally.

- (b) Buyer shall be responsible for conducting any microbiological testing with respect to the Product. Such testing shall be conducted in such manner as Buyer shall determine. Buyer acknowledges that Seller shall not be conducting any microbiological testing. Within 90 calendar days of execution of this Agreement and biannually during the term of this Agreement, a review of Product Specifications shall be completed jointly by Buyer and Seller to ensure conformity.
- (c) In the event of any non-conformance, Seller within a reasonable period of time shall: (i) arrange for return to Seller or an Affiliate of Seller, at Seller's sole cost and expense, such Products as are finally determined to be out of conformance with the Product Specifications; (ii) replace such Products as are finally determined to be out of conformance with the Product Specifications; and (iii) compensate Buyer for the freight costs, including cleaning and sanitization as required of any carload rejected for nonconformance in accordance with this Section 4.
- (d) Any shipment of Products for which Buyer shall not submit a Claim within sixty (60) calendar days of receipt shall be deemed accepted. Upon acceptance, Buyer shall release Seller from all Claims for non-conformity or defects except Claims for latent defects which are not reasonably detectable at the time of acceptance.
- (e) In the event any governmental agency having jurisdiction shall request or order, or if Buyer shall determine to undertake, any corrective action with respect to Products supplied hereunder, including any Product recall, customer notice, restriction, change, corrective action or market action or any Product change, and the cause or basis of such corrective action is attributable to a breach by Seller of any of its warranties, guarantees, representations, obligations or covenants contained herein, then Seller shall be liable, and shall reimburse Buyer for the reasonable costs of such action including the cost of any Product affected thereby whether or not such particular Product shall be established to be in breach of any warranty by Seller hereunder *provided, however*, that Seller's obligation to indemnify Buyer hereunder shall not exceed Twenty Million Dollars (\$20,000,000) in the absence of Seller's gross negligence or willful misconduct, and Forty Million Dollars (\$40,000,000) in the event of Seller's gross negligence or willful misconduct.

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- (f) Seller will provide Buyer with all such technical assistance and training as may be required by Buyer to maintain satisfactory Product performance.

5. Inspection.

Buyer shall have the right, upon reasonable notice to Seller and during regular business hours, to inspect and audit the facilities being used by Seller for production of the Products to assure compliance by Seller with applicable rules and regulations and with other provisions of this Agreement and to determine Seller's raw materials and manufacturing costs in connection with the Products to the extent these costs are passed on to Buyer. Seller shall within seven calendar days remedy any deficiencies which may be noted in any such audit, and the failure by Seller to remedy any such deficiencies within such seven day period shall be deemed to be a material breach of this Agreement; provided, however, that if such deficiency is not capable of being remedied within such seven (7) day period, then so long as Seller is pursuing in diligent fashion a commercially acceptable remedy to such deficiency it shall not be deemed to be a material breach. Seller acknowledges that the provisions of this Article granting Buyer certain audit rights shall in no way relieve Seller of its obligations under this Agreement, nor shall such provisions require Buyer to conduct any such audits.

6. Warranty.

- (a) Seller represents and warrants to Buyer that all Products sold by Seller shall (i) conform to the quality standards set forth in Annex A and (ii) be in compliance with all applicable federal, state or municipal statutes, laws, rules or regulations, including those relating to the environment, food or drugs and occupational health and safety. Without limiting the foregoing, Seller represents and warrants that it shall comply with all present and future statutes, laws, ordinances and regulations relating to the manufacture, assembly and supply of the Products being provided hereunder, including without limitation, those enforced by the United States Food and Drug Administration (including compliance with good manufacturing practices) and International Standards Organization Rules 9,00 et. seq. Seller further represents and warrants to Buyer that the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under its Certificate of Incorporation or corporate bylaws or any agreement, contract, commitment or obligation to which Seller or any of its Affiliates is a party or by which it is bound. **EXCEPT FOR THE WARRANTIES CONTAINED IN THIS AGREEMENT, SELLER MAKES NO OTHER**

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WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, IN FACT OR BY LAW, WHETHER OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE OR OTHERWISE.

- (b) Seller has read and understands the Johnson & Johnson Policy on the Employment of Young Persons (the "Policy"). In the manufacture of the Products, Seller shall employ young persons only as permitted by the Policy. Seller shall permit representatives of Buyer to enter Seller's premises at any reasonable time to inspect relevant employment, health and safety records and to observe the manufacturing process. Seller shall maintain the records necessary to demonstrate compliance with the Policy and shall provide to Seller a written certification of such compliance annually during the term of this agreement. If Seller shall fail to comply with this provision, then Buyer shall have the right to terminate this agreement forthwith and without penalty.

7. Indemnification.

- (a) Buyer and Seller agree that liability for damages alleged to have been suffered by Buyer and Seller arising out of an alleged breach of Section 6(a) or otherwise under this Agreement shall be handled as follows:
- (i) Seller shall indemnify Buyer for any cost, loss, damage or expense suffered by Buyer which arises from: (A) the Product not meeting the specifications therefor as described in Annex A at the time title for such Product passed to Buyer, except for the microbiological specifications set forth therein; or (B) Seller failing to sample and test Products in accordance with the sampling and testing methods described in Annex A in the manner practiced by Seller on the date of this Agreement or as modified by the mutual agreement of the parties pursuant to Section 1 (b) above; *provided, however*, that Seller's obligation to indemnify Buyer shall not exceed Twenty Million Dollars (\$20,000,000) in the absence of Seller's gross negligence or willful misconduct, and Forty Million Dollars (\$40,000,000) in the event of Seller's gross negligence or willful misconduct.
- (ii) Seller shall be solely liable in the event that the Product failed to conform to the microbiological quality standards as set forth in Annex A before title to such Products passed from Seller to Buyer; *provided, however*, that Seller's liability pursuant to this Section 7 (a) (ii) shall be limited to replacement of Products and reimbursement of certain of

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Buyer's freight costs, including railcar cleaning and sanitization, in accordance with Sections 4 (c) above.

- (iii) Buyer shall be solely liable for, and shall indemnify Seller for any cost, loss, damage or expense suffered by Seller arising out of the failure of the Products to conform to the microbiological quality standards established therefor, as the same may be amended from time to time.
 - (iv) Excluding those matters set out in the preceding clauses (i), (ii) and (iii), Seller shall indemnify, defend and hold harmless Buyer and its Affiliates, and each of their respective officers, directors, agents and employees from and against all liabilities arising out of any violation by Seller of any law, ordinance, regulation or rule or the order of any court or administrative agency, and from and against all liabilities arising out of any claim by an employee, agent, or contractor of Seller arising in connection with this Agreement, *provided however*, that Seller shall not indemnify Buyer for any such liabilities to the extent that such liabilities arise from: (i) the acts or omissions of Buyer; or (ii) the acts or omissions of Seller which were directed by Buyer.
- (b) The provisions of this Section 7 shall survive any termination or expiration of this Agreement.

8. Term; Termination.

- (a) The term of this Agreement shall be for a period of 3 years beginning on April 15, 2001, unless sooner terminated pursuant to this Agreement.
- (b) Either party may terminate this Agreement for any reason by giving notice to the other party of its intent to terminate at least 365 calendar days prior to the date on which it seeks to terminate this Agreement.
- (c) This Agreement may be terminated, prior to the expiration of its term, upon fifteen (15) calendar days written notice by either party:
 - (i) in the event that the other party hereto shall (A) apply for or consent to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (B) make a general assignment for the benefit of its creditors, (C) commence a voluntary case under the United States Bankruptcy Code, as now or hereafter in effect (the "Bankruptcy Code"), (D) file a petition seeking to take advantage of any law (the "Bankruptcy Laws") relating to

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bankruptcy, insolvency, reorganization, winding-up, or composition or readjustment of debts, (E) fail to controvert in a timely and appropriate manner, or acquiesce in writing to, any petition filed against it in any involuntary case under the Bankruptcy Code, or (F) take any corporate action for the purpose of effecting any of the foregoing; or (ii) if a proceeding or case shall be commenced against the other party hereto in any court of competent jurisdiction, seeking (A) its liquidation, reorganization, dissolution or winding-up, or the composition or readjustment of its debts, (B) the appointment of a trustee, receiver, custodian, liquidator or the like of the party or of all or any substantial part of its assets, or (C) similar relief under any Bankruptcy Laws, or an order, judgment or decree approving any of the foregoing shall be entered and continue unstayed for a period of 60 calendar days; or an order for relief against the other party hereto shall be entered in an involuntary case under the Bankruptcy Code.

- (d) This Agreement may be terminated, prior to the expiration of its term, by either party by giving written notice of its intent to terminate and stating the grounds therefor if the other party shall materially breach or materially fail in the observance or performance of any representations, warranty, guarantee, covenant or obligation under this Agreement, and such breach or failure is not the result of an Event of Force Majeure (as such term is defined in Section 9 below). The party receiving the notice shall have thirty (30) calendar days from the date of receipt thereof to cure the breach or failure; or, in the event that such breach or failure is not reasonably susceptible to cure within such time, to commence and diligently pursue good faith efforts to cure such breach within such time as may be reasonable in the circumstance. In the event such breach or failure is cured, the notice shall be of no effect.
- (e) Notwithstanding the termination of this Agreement for any reason, each party hereto shall be entitled to recover any and all damages which such party shall have sustained by reason of the breach by the other party hereto of any of the terms of this Agreement. Termination of this Agreement for any reason shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination. In the case of a termination under Section 8 (d) above, the non-defaulting party may pursue any remedy available in law or in equity with respect to such breach, subject to Section 15 hereof.

9. Force Majeure.

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- (a) If either party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a "Force Majeure Event"), such non-performing party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused for three months or as long as such event shall be continuing (whichever occurs sooner), provided that the non-performing party give immediate written notice to the other party of the Force Majeure Event. Such non-performing party shall exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.
- (b) Notwithstanding the provisions of Section 9 (a) above, in the event that due to the occurrence of an Event of Force Majeure, Seller shall be unable to supply Products in such quantities as Buyer shall request and in compliance with the delivery periods set forth in this Agreement, Buyer shall be permitted (with no obligation to Seller) to obtain Products from another source, and Buyer shall thereafter have no obligation to purchase Products from Seller until any contractual obligations that Buyer has assumed in connection with obtaining a substitute supply of Products shall have terminated. Buyer shall have no obligation to affirmatively terminate any such contractual arrangements.
- (c) In the event that such an alternative supplier is established, Seller shall use its best efforts to give Buyer access to any proprietary technical materials, information and techniques necessary or helpful for Buyer to arrange an alternative supplier of Product, and to provide advice and consultation in connection therewith. The provision of any proprietary information by Seller shall be subject to the recipient entering into reasonable confidentiality obligations with Seller as well as a commitment by the recipient that such proprietary information shall only be used for purposes of providing substitute Product to Buyer.

10. Confidentiality.

As used herein, "Confidential Information" shall include all information given to, or otherwise acquired by a party hereto, relating to the other party's business or affairs, including without limitation: (i) information regarding any of the products of a party or the design or manufacture of

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such products or the packaging thereof; (ii) information regarding advertising, distribution, marketing or strategic plans; (iii) information regarding costs, productivity or technological advances; (iv) any designs, specifications, blueprints or patterns ;or (v) the terms and conditions of this Agreement; or (vi) any other information received by a party in connection with its performance of the obligations contemplated under this Agreement. Neither party shall use or disclose, but shall insure that its employees, officers and agents shall not use or disclose (except, in either case, to comply with a party's obligations under this Agreement or the rules of any stock exchange), any Confidential Information to third parties. Upon the termination or expiration of this Agreement each party shall return to the other party all Confidential Information in written form. This Section 10 shall survive the termination or expiration of this Agreement for a period of five (5) years. Confidential Information shall not include information that (vii) was already known to the other party at the time of its receipt thereof, as evidenced by competent evidence, (viii) is disclosed after its receipt thereof by a third party who has a right to make such disclosure without violating any obligation of confidentiality, (ix) is independently developed by a party or (x) is or becomes part of the public domain through no fault of any party hereto. For purposes of this Section 10, a reference to a "party" or to Buyer or Seller shall include Affiliates of the referenced party.

11. Compliance with Certain Laws.

Seller agrees to comply with the applicable provisions of any federal (United States or otherwise) or state law and all executive orders, rules and regulations issued thereunder, whether now or hereafter in force, including Executive Order 11246, as amended; Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of race, color, religion, sex or national origin; Section 60-741.1 of Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap; Section 60.250.4 of Chapter 60 of Title 41 of the Code of Federal Regulations, as amended, providing for the employment of disabled veterans and veterans of the Vietnam era; Chapter 1 of Title 48 of the Code of Federal Regulations, as amended, pertaining to the Federal Acquisition Regulations; Sections 6, 7 and 12 of the Fair Labor Standards Act, as amended, and the regulations and orders of the United States Department of Labor promulgated in connection therewith; and any provisions, representations or agreements required thereby to be included in this Agreement are hereby incorporated by reference. If any Products are ordered by Buyer under U.S. government contracts, Seller agrees that all applicable federal statutes and regulations

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applying to Buyer as contractors are accepted and binding upon Seller insofar as Seller may be deemed a subcontractor.

12. Insurance.

Seller agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby which policies shall provide for the type of insurance and amount of coverage described in Annex C. Upon Buyer's request, Seller shall provide to Buyer a certificate of coverage or other written evidence reasonably satisfactory to Buyer of such insurance coverage.

13. Relationship of the Parties.

The relationship of Buyer and Seller established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to: (i) give either party any right or authority to create or assume any obligation of any kind on behalf of the other or; (ii) constitute the parties as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking.

14. Publicity.

Neither party shall originate any publicity, news release, or other announcement, written or oral, whether to the public, the press, the trade, Buyer's or Seller's customers or otherwise, relating to this Agreement, or to performance hereunder, or to the existence of an arrangement between the parties, without the prior written approval of the other party. Neither party shall use the name of the other party for advertising or promotional purposes without the prior written consent of such party.

15. Construction.

This Agreement shall be governed by, and shall be construed in accordance with, the laws of the State of New Jersey. Any controversy or claim arising out of or relating to this Agreement, or the parties' decision to enter into this Agreement, or the breach thereof, shall be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The arbitration shall be held in New Jersey and arbitrators shall apply the substantive law of New Jersey except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. The arbitrators shall not award any of the parties punitive damages and the parties shall be deemed to have waived any right to

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such damages. This Section 15 shall survive any termination of this Agreement.

16. Entire Agreement.

It is the mutual desire and intent of the parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The parties have, in this Agreement, incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither party makes any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement and the Annexes attached hereto, which are by this reference incorporated herein: (i) constitute the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises, representations, conditions, provision or terms related thereto other than those set forth in this Agreement, and (ii) supersede all previous understandings, agreements and representations between the parties, whether written or oral. No modification, change or amendment to this Agreement shall be effective unless in writing signed by each of the parties hereto. Notwithstanding the foregoing and for clarification purposes, to the extent that any of the provisions of the previous supply agreement between Buyer and Seller for the Product survive the expiration and/or termination of such earlier supply agreement, then those surviving terms or provisions shall continue in effect as provided for in such earlier supply agreement.

17. Headings.

The headings used herein have been inserted for convenience only and shall not affect the interpretation of this Agreement.

18. Notices.

All notices and other communications hereunder shall be in writing, and shall be: (i) delivered personally; (ii) mailed by certified or registered U.S. mail, return receipt requested, postage prepaid; or (iii) sent by Federal Express or another nationally recognized courier service (billed to sender), to the parties at the following addresses:

If to Seller: President
Luzenac America, Inc.
9000 East Nichols Avenue
Englewood, Colorado 80112

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If to Buyer: Purchasing Manager
Johnson & Johnson
Consumer Products Companies
Shared Services Purchasing
P. O. Box 587
545 Old Elbert Road
Royston, Georgia 30662

or to such other place as either party may designate by written notice to the other. Such notices shall be deemed given (i) upon personal delivery; (ii) three business days after such deposit in the U.S. mail; or (iii) upon delivery by such courier service.

19. Failure to Exercise.

The failure of either party to enforce at any time for any period any provision hereof shall not be construed to be a waiver of such provision or of the right of such party thereafter to enforce each such provision, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy. Remedies provided herein are cumulative and not exclusive of any remedies provided at law.

20. Assignment.

This Agreement may not be assigned by either party without the prior written consent of the other, except that Buyer and Seller may assign their rights and/or obligations hereunder to any of their respective Affiliates, and except that Buyer may assign its rights and/or obligations hereunder to any successor to all or substantially all of Buyer's assets which relate to the Product. Subject to the foregoing sentence, this Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns.

21. Severability.

Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by this Agreement to both parties remain substantially unimpaired, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

22. Definitions.

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- (a) For purposes of this agreement, an "Affiliate" of a party to this Agreement shall mean any corporation or partnership or other entity which directly or indirectly controls, is controlled by or is under common control with such party. "Control" shall mean the legal power to direct or cause the direction of the general management or partners of such entity whether through the ownership of voting securities, by contract or otherwise. "Affiliate" shall also include any party manufacturing talc-containing body powders for, on behalf of, or under license or other authority of Buyer or Buyer's Affiliates.
- (b) "Contract Year" shall mean the twelve-month period commencing on April 15th of any year during the term of this Agreement and concluding on April 14th of the next succeeding year.

23. Equipment.

- (a) Buyer has made and may make available certain equipment, such as railcars (the "Equipment") for Seller to use in manufacturing the Products or otherwise preparing the Products for delivery. Seller shall have no ownership or leasehold interest of any nature in the Equipment and all right, title and interest in the Equipment shall remain with the Buyer. From time to time at the request of the Buyer and in connection with the Equipment, Seller will execute one or more financing statements, information statements and/or continuation statements pursuant to the Uniform Commercial Code in such form or forms as Buyer may request for filing in such public offices as Buyer shall determine.
- (b) Buyer shall have the right to enter Seller's facilities in order to (i) inspect the Equipment, (ii) inspect and copy all records relating to the repair, maintenance and servicing by Seller of the Equipment and (iii) affix tags, stickers or other items to the Equipment indicating Buyer's status as owner thereof. Buyer shall be given access to such facilities, on reasonable notice, during normal business hours and at any other time when work is performed pursuant to this Agreement.
- (c) During the term of this Agreement, Seller shall (i) be responsible for any damage to the Equipment, (ii) keep the attachments, security interests or other claims that could affect title to the Equipment of Buyer's interest therein, (iii) not modify or alter the Equipment in any way, (iv) not remove, conceal or deface any tags, sticker or other items affixed to the Equipment that indicate Buyer's status as owner thereof, (v) operate the Equipment in accordance with good business practice and in compliance with all written and verbal instructions provided to Seller and (vi) not use the Equipment for

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any purpose except to provide Products to Buyer pursuant to this Agreement.

- (d) During the term of this agreement Buyer shall service, repair and maintain (collectively, "Service") the Equipment as may be necessary to keep the Equipment in good working order.
- (e) Seller shall be responsible for training its employees to operate properly the Equipment and shall supervise all operations thereof. Seller shall be responsible for all personal damages or injuries and for any damage to property or Equipment resulting from (i) Seller's operation of the Equipment, (ii) Seller's failure to arrange with Buyer for required Service of the Equipment or (iii) Seller's use of the Equipment for any purpose other than as specifically contemplated in this Agreement.
- (f) In the event that this Agreement is terminated for any reason, Buyer shall have the right to enter, upon reasonable notice and during regular business hours, and shall be given access to, Seller's facilities so that Buyer may retrieve the Equipment and all records maintained in connection with the Equipment. Seller agrees to cooperate with Buyer to ensure the timely and safe return of the Equipment to Buyer after termination of this Agreement. Seller's obligations under this Section shall survive the termination of this Agreement until the Equipment is returned to Buyer.
- (g) Seller shall maintain insurance coverage in connection with its operation of the Equipment as described in Annex C.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized respective representatives as of the day and year first above written.

LUZENAC AMERICA, INC.

By: [Signature]
Name: DANIEL D HARRIS
Title: PRESIDENT

**JOHNSON & JOHNSON
CONSUMER COMPANIES, INC.**

By: [Signature]
Name: Robert E. Kirby
Title: Vice President

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ANNEX A

PRODUCT SPECIFICATIONS

- Material Specification RM08006 Luzenac America, Inc., Windsor Grade 66 Talc

Which references the following:

- Standard Operating Procedures:
 - SOPB30 INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.
- Test Methods:
 - TM7024 ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY
 - TM7070 FINENESS DETERMINATION OF CERTAIN POWDERS VIA AIR-JET SIEVE
 - TM7071 COLOR DETERMINATION OF WINDSOR 66 TALC
 - TM7077 CARBONATES IN TALC
 - TM7164 LOSS ON DRYING (OVEN - 105°C)
 - TM7165 SOLUBILITY IN ACID (TALC)
 - TM7166 BULK DENSITY (POWDERS)
 - TM7167 FINENESS (SIEVE ANALYSIS)
 - TM7168 HEAVY METALS
 - TM7169 ARSENIC CONTENT (TALC)
 - TM7170 COLOR
 - TM7171 SOLUBILITY IN ACID (MAGNESIUM CARBONATE TITRATION)
 - TM7252 VISUAL
 - TM7716 LECO CARBON DETERMINATOR FOR USE IN INSOL & MAGNESITE ($MgCO_3$) % DETERMINATION
 - TM7177 ATOMIC ABSORPTION SPECTROPHOTOMETRY IN DETERMINING ARSENIC CONTENT OF TALC
 - TM7807 MICROBIAL EVALUATION OF RAW MATERIAL TALC AND RAW CORNSTARCH

All referenced documents attached hereto.

Material Specification

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: RM08006

Franchise: Adult/Kids/Baby

Location: ROYSTON, KOLMAR,
 SILLIKER (NJ)

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL
Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

REVISION	AUTHORIZATION	DESCRIPTION OF CHANGE
01/31/95	CR019240	Location revised. Product Page deleted. (M. Frazee)
07/20/95	CR021423	Location revised. Requirements for Micatin added and Specification re-formatted per QAP00037. Section 7.0, Microbial Req, Frequency revised. Note 1.C.3 updated. Sec. 9.3, Sampling Req. at Kolmar, Analytical updated and Sec. 9.4, Characteristics revised. (F. Holub)(908-874-1842)
08/17/95	CR021933	Section 10.1, Microbial Release Criteria, revised. (M. Caganek)(908-874-1419)
03/15/96	CR023882	Sec. 9.3 SAMPLING REQUIREMENTS AT KOLMAR, for Microbiological revised. (M. Munshi)(908-874-1839)
09/30/96	CR025300	Sec. 7.0, Luzenac Technical Center included in Note 1A. Note 1B changed from J&J to Luzenac. Note 1D added for heavy metals testing of yearly composite. Sec. 9.4, SOPB30 added under testing requirements, and Royston requirements for Ship to Production. (R. Corder)(706-245-2024)
09/23/97	CR028951	Sec. 2.7 COLOR, revised to include Luzenac test method STM76 with a minimum requirement of 84.5 reflectance. Company name updated. (C. Wilkes)(706-245-2101)
03/09/00	CR217132	Sec. 5.0, removed Hammondsville Mine as an approved mine. (M. Underwood) (706-245-2078)



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Document No.: RM08006**Franchise:** Adult/Kids/Baby**Location:** ROYSTON, KOLMAR,
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1.0 DESCRIPTION

A hydrous magnesium silicate (also called magnesium acid metasilicate), a fine white lustrous powder, slippery, adherent to skin with no foreign odor or grittiness.

2.0 PROPERTIES & REQUIREMENTS

2.1 Infrared Identification (CTFA/G3-1)

The infrared spectrum of the sample should exhibit absorption bands of the sample pattern and placement as those exhibited by the standard, with no extraneous bands present, as determined by a qualified analyst.

2.2 Asbestos (CTFA/J4-1, J6-1)(TM7024)

None detected. Asbestos is defined to be the fibrous serpentine, chrysotile and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite and actinolite.

3.0 CERTIFICATE OF ANALYSIS

A silo source analytical certificate will provide numerical analytical results required for items 3.1-3.6 and 3.10 below. Secs. 3.7-3.9 below will be reported as pass/fail. These results are obtained from a silo composite sample which is comprised from samples taken at eight hour intervals during the filling of the silo. The silo source analytical certificate will reference the railcar or trailer number(if a trailer is used to ship directly to Royston) or lot number of bags.

The certificate of analysis and the railcar/ or trailer seal log required as per SOPB30 will accompany the preshipment samples to Royston and will be sent to the Royston Microbiology Laboratory.

The Certificate of Analysis is an Acceptance/Rejection criteria.

3.1 Moisture (TM7164)

NMT 0.15%

3.2 Solubility by Acid (TM7165)

NMT 2.0%

3.3 Magnesite (MgCO₃)%(TM7171 or TM7077 or TM7716)

NMT 1.10% MgCO₃

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Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

3.4 Bulk Density (TM7166)

20.5 to 25.5 lb./cu. ft. or metric equivalent at Windsor Location.

3.5 Color (TM7170 or TM7071 or STM76)

White as compared to a previously accepted lot, a minimum of 85.5 reflectance reading for TM7071 or a minimum of 84.5 reflectance for Luzenac test method STM76 Minolta Color Analysis.

3.6 Fineness (TM7070 or TM7167)

Through 60 mesh, 100%. Through 100 mesh, at least 99.7%, through 200 mesh, at least 98.5%.

3.7 Heavy Metals (TM7168)

NMT 10 ppm

3.8 Arsenic (TM7169 or TM7717)

NMT 2.5 ppm

3.9 Water Soluble Iron (USP)

Pass Test

3.10 Microbial Requirement (TM7807)

Samples taken from Windsor silos, trucks or bags shall contain no detectable harmful microorganisms and the total count shall be no greater than 50 microorganisms per gram of product. (See section 7 for details of testing)

4.0 PACKING, MARKING & STORAGE

4.1 Packing

In suitable bags to protect contents from loss, contamination and deterioration in normal shipment and storage. Pallets of bagged material must be either stretch wrapped or covered with corrugated and secured with straps. Each bag shall contain 50 lbs. or metric equivalent. Bulk shipments will be made in CPC approved railcars and trailers.

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Expiration Date: None

Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

4.2 Marking

Each bag shall be marked with:
Contents Name, Supplier
Name, Supplier Lot No.
Net Weights
Purchaser's Code

Bulk shipments are identified by the individual number of the particular trailer or railcar.

4.3 Storage

If stored in bags, keep in dry area. Suitable bulk silos (for CPC): Buttlar electro-fused polymer utilizing white flint-flex powder #531-7010 manufactured by DuPont.

5.0 ACCEPTANCE

There shall be no change in the supplier's process or composition of the material without prior notification to and approval of JOHNSON & JOHNSON. Any non-conformance to the specified Description/Properties & Requirements, shall be cause for rejection.

The following mine properties in Vermont are qualified and approved to provide ore for processing into Grade 66 talc: Argonaut Mine, Rainbow Mine, Hamm Mine (Windham).

6.0 RAILCAR LOADING & SAMPLING

Railcar loading, unloading and sampling shall be in accordance with the approved J&J Consumer Products Procedure SOPB30.

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Expiration Date: None

Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

7.0 FREQUENCY OF CHARACTERISTICS TO BE TESTED

<u>No.</u>	<u>Characteristic</u>	<u>T.M.</u>	<u>Frequency</u>
2.1	Infrared ID	CTFA/G3-1	Per Note 1C
2.2A	Asbestos(a)	CTFA/J4-1,J6-1	Per Note 1A
2.2B	(b)	TM7024	Per Note 1B
3.1	Moisture	TM7164	Certified per 2a
3.2	Solubility by Acid	TM7165	Certified per 2a
3.3	Magnesite (MgCO ₃)%	TM7171/TM7077/ TM7716	Certified per 2b
3.4	Bulk Density	TM7166	Certified per 2b
3.5	Color	TM7170/TM7071/ STM76	Certified per 2b
3.6	Fineness	TM7167 or TM7070	Certified per 2b
3.7	Heavy Metals	TM7168 BPT148, and modified TM7165	Certified per 2a 1D
3.8	Arsenic	TM7169 or TM7717 BPT148, and modified TM7165	Certified per 2a 1D
3.9	Water Soluble Iron	USP	Certified per 2a
3.10	Microbial Req.	TM7807	Every silo-See3a Every railcar 3b Per Section 4.0, Sampling Requirement at Kolmar

NOTE:

1A. A composite sample is made from every two completed silos, labeled with silo numbers and production dates and forwarded to the Luzenac America Technical Center, Englewood, Co. Luzenac will perform the x-ray diffraction as per CTFA J4-1 and J6-1. Results are reported to Johnson & Johnson CPC, Royston, GA.

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Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

- 1B. Quarterly composite samples of above silo samples will be evaluated by TM7024 by Luzenac America and data reported to Johnson & Johnson CPC, Royston, GA.
- 1C. For transfer of preapproved raw material to a new location only.
- 1D. Luzenac will make a yearly composite of the quarterly samples and analyze for heavy metals (Fe, Ni, Mn, Co, Cu, Cr, Cd, Pb and As) by BPT 148. The Pb and As are to be analyzed by the same method, but with the following modifications: 5 gm of talc is first extracted in dilute hydrochloric acid according to TM7165 and the final dilution of the extracted solution is changed from 100ml to 50ml. Results of yearly composite are sent to J&J CPC.
2. Certificates of Analysis are received from Luzenac America with each pre-shipment microbial sample. Analytical testing frequencies.
- a. Tested on silo composite after each silo is filled.
- b. Tested in two hour composite samples. Each silo is released on the average result of all the two hour composite sample results.
3. Microbial
- a. Microbial testing performed on flash dried samples taken as the silo is being filled to represent a stratified sampling of at least 30 samples. (Royston is used as the testing lab.)
- b. Microbial testing will be conducted on the pre-shipment composite sample of each railcar taken as per SOPB30.

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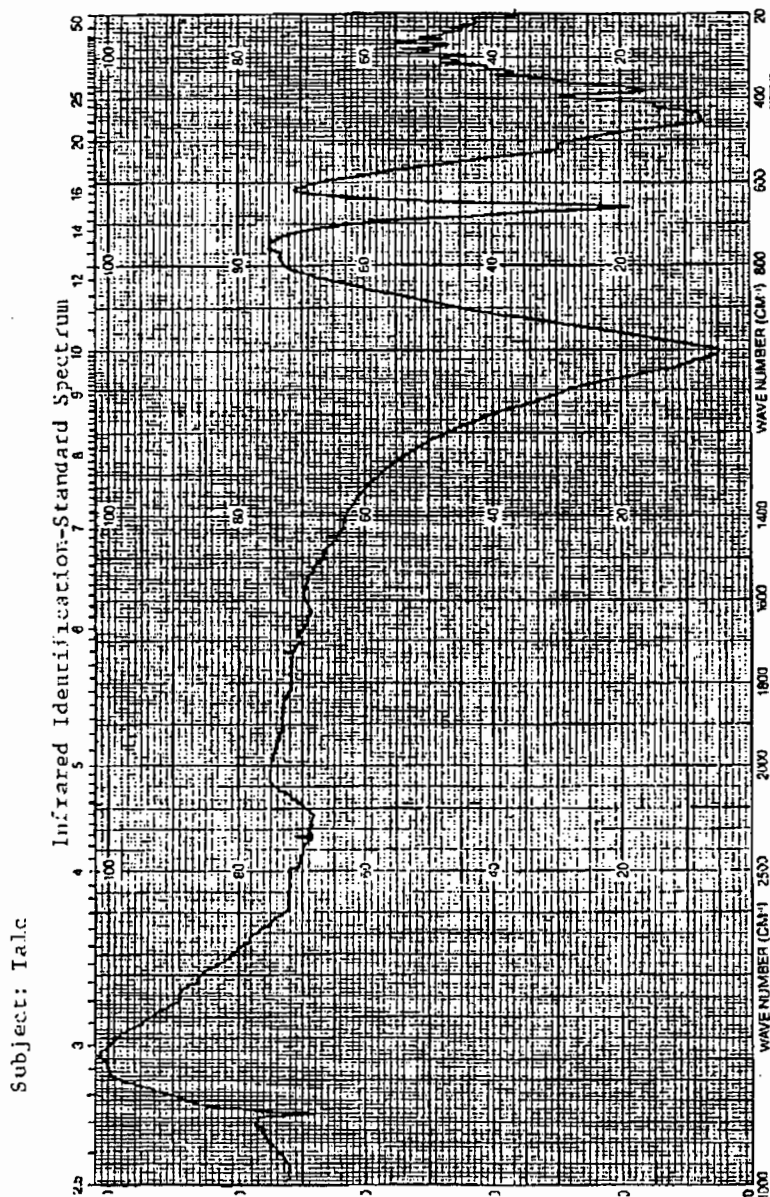
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Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

8.0 IR PAGE



Scan Speed: 6 min
 Split: N
 Sampling: K3r
 Cell Type: NA

Tr: CTA 63-1
 Analyst: L. Farinich
 Date: 3-3-92
 Ref: 1370-159

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Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

9.0 QUALITY ASSURANCE INFORMATION FOR MANUFACTURING LOCATION USE ONLY

9.1 RECEIVING INSPECTION AT ROYSTON & KOLMAR:

<u>Characteristic</u>	<u>Test Method</u>	<u>Frequency</u>
Approved Supplier	TM7252	Every receipt
Certification of Analysis	TM7252	Every receipt

9.2 APPROVED SOURCES

<u>Manufacturing Location</u>	<u>Trade Name</u>
Luzenac America, Inc. P.O. Box 680 Windsor, VT 05089	Windsor 66

Distribution Location: Same

Specification Mailing Location: Same

Approved Bulk Tank Cleaning Facility

Rail Services, Inc.
 Calvert City, KY

9.3 SAMPLING REQUIREMENTS AT ROYSTON: Shall be in accordance with approved J&J CPC SOPB30.

CPC acceptable limit on samples taken from railcars or trucks at receiving point is 20.5-27.0 lb/cu. ft.

IMPORTANT! ANY CHANGES TO THIS SPECIFICATION OR THE TALC PROCESS MUST BE EVALUATED FOR POTENTIAL IMPACT ON MICRO AUDIT TESTING OF FINAL POWDER PRODUCTS AT ROYSTON.

SAMPLING REQUIREMENTS AT KOLMAR:

Analytical: 1 x 4 oz. sample labeled analytical.

Microbiological: (Square root of n) +1 bags in the shipment for each lot, tested in composites of not more than 5 samples by Silliker Labs of NJ, 400 South Ave., Garwood, N.J. 07027 (Contact: Janice Fuls)

Retain: 16 oz. per lot per shipment.

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Expiration Date: None

Subject: LUZENAC AMERICA, INC., WINDSOR GRADE 66 TALC

9.4 TESTING FREQUENCIES AND REQUIREMENTS

Royston: As follows:

<u>Characteristic</u>	<u>T.M.</u>	<u>New Lot</u>	<u>Old Lot</u>	<u>Retest</u>	<u>STP</u>
Microbial Content	SOPB30	Every Lot	Every Lot	12 Months	Every Lot

Kolmar: As follows:

<u>Characteristic</u>	<u>T.M.</u>	<u>New Lot</u>	<u>Old Lot</u>	<u>Retest</u>	<u>STP</u>
Microbial Content	TM7807	Every Lot	Every Lot	12 Months	N/A
Analytical Testing Infrared ID	CTFA/ G3-1	Every Lot	Every Lot	12 Months	N/A

New Lot: First receipt of a specific lot. For materials on reduced testing, testing frequency must insure that each characteristic is tested at least once per year.

Old Lot: Subsequent receipts of a previously accepted lot received with 12 months of the original receipt. Receipts after 12 months are new lots. Previously rejected lots are to be rejected.

Retest: To assure continued conformance, lots in inventory must be retested. Frequency interval is from last test date.

STP: Ship to Production suppliers only. For materials from suppliers not designated as Ship to Production (see Approved Suppliers) material must be evaluated per New Lot/Old Lot frequencies.

N/R: Not required

N/A Not applicable

C of A Must certify characteristics listed in section 2.0. For characteristics tested by the receiving location, the C of A is not an accept/reject criteria. For characteristics which are not tested, certification must be received via C of A for release.

Standard Operating Procedure

Company:

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Document No.: SOPB30

Franchise:

Location: ROYSTON - OS

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

Approval Routing

PRIMARY RESPONSIBLE OFFICIAL (PRO): B. Chen

ORIGINATOR: R. Corder

QUALITY SERVICES: J. Slade

OTHERS: N/A

REVISION

AUTHORIZATION

DESCRIPTION OF CHANGE

February 4, 1992

New SOP.

July 21, 1992

Updated procedure.

September 30, 1993

Added requirements for monthly sample under Section 6.1. Changed name from Cyprus to Luzenac. Updated with current address.

06/14/95

CR021410

Changed pro from M. Roser to B. Chen. Changed title to correct loading location and grade. Updated procedure for sampling in Sec. 5 to change from bags to cups. Changed all references from Cyprus to Luzenac. Exhibit II revised. (R. Corder)

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Document No.: SOPB30

Franchise:

Location: ROYSTON - QS

Document Type: Permanent

Expiration Date: None

Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

1.0 Purpose:

To establish procedures to control the inspection, sampling and loading of PD 5000 rail cars with Grade 66 talc for shipment to CPI, Royston, Ga. The correct use of this procedure prevents contamination of the rail cars.

2.0 Scope:

This procedure is used at the Luzenac rail car loading site located in Ludlow Vt.

3.0 References:

N/A

4.0 Procedure:

4.1 QUALIFIED VENDOR LOCATION:

The qualified supplier loading location is Luzenac, Ludlow, Vt.

4.2 INSPECTION PROCEDURE:

Each rail car is to be inspected upon receipt, and prior to loading. All hatches, valves, and seals are to be checked for integrity. Absence of water and/or moisture should be verified prior to loading by opening the one top hatch that will be used with the dust collector system (after seal verification) and inspecting that compartment.

5.0 MICROBIOLOGICAL SAMPLING:

The sampling of Luzenac America, talc 66 used in each talc shipment shall be performed in accordance with the procedure outlined below:

5.1 Rail car sampling - The following talc samples will be aseptically collected from each rail car loading on a regular basis. **Note:** Once each month, a microbial sample is also taken from the product line just before the car is filled. Wear disposable surgical gloves and use a sterile spatula to put the talc in the sterile container. This sample is sent with the preshipment samples.

5.2 Sample Requirements

A composite talc sample (8 oz. minimum) will be aseptically collected from each trailer used in loading the rail car. The composite sample will be collected using an auto sampler which is positioned in-line in the delivery system between the trailer just prior to the talc entering the rail car.

Standard Operating Procedure

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Franchise:

Location: ROYSTON - QS

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Expiration Date: None

Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

- 5.3 Sampling procedure - The following procedure should be utilized for the aseptic sampling of talc rail cars using the automatic rail car sampler.

NOTE: The entire auto sampler device is to be sanitized using 70% IPA prior to installation. If the sampler is removed for any reason from the line it must be re-sanitized prior to reinstallation. The section of the auto sampler which contains the sample canister must be housed under a protective cover to prevent contamination of the sample during inclement weather. The auto sampler will be a Gustafson Automatic Sampler Model R or equivalent.

- 5.3.1 Using the manufacture's instructions, set the auto sampler to take a sample every seven minutes until a minimum of an 8 oz. sample is obtained. This sample size is per trailer used to fill the rail car.
- 5.3.2 Spray exterior of sampling lines and "protective" specimen cup with 70% isopropyl alcohol (IPA) if more than 24 hours have passed between an unloading of a trailer.
- 5.3.3 Remove the specimen cups.
- 5.3.4 Use sterile gauze soaked with 70% IPA to sterilize the inside of the top portion of the automatic sampler (use surgical gloves sprayed with IPA in this procedure.)
- 5.3.5 Remove a sterile specimen jar from its protective wrapper and remove the lid. Store the lid on the unused "protective" cup. Caution must be taken to ensure the cup and lid do not become contaminated. Two cups at a time will be used to sample each bulk trailer (one on each end of the "Y" of the sampler). Two sets of sample cups (four cups) will be necessary for each trailer load.
- 5.3.6 Connect the sterile cups to the sampler; one on each end of the "Y" on the sample discharge
- 5.3.7 Remove the first set of sample cups halfway through the unloading of a trailer. Place the specimen cups into two separate sample bags labeled with information as specified in 5.3.10. Place second set of sample cups on the sampler following steps 5.3.5 and 5.3.6.
- 5.3.8 Leave second set of sample cups on sampler until pumping is complete. Remove second of sample cups and place one into each of the sample bags containing the first set of samples.
- 5.3.9 Replace the "protective" specimen cups onto each line of the sampler.

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Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

5.3.10 Write the following information on each of the sample bags that contain the specimen cups.

5.3.10.1 Rail car number, trailer number and Silo number.

5.3.10.2 Date loaded.

5.3.11 If the next trailer is to be connected and pumped immediately, repeat steps 5.3.3 through 5.3.9.

5.3.12 Repeat steps 5.3.3 through 5.3.9 for each trailer.

5.3.13 Once per week replace "protective" specimen with a new sterile cup.

5.3.14 Send one complete set (8 cups per rail car) to:

J & J Consumer Products Company
P. O. Box 587
545 Old Elbert St.
Royston, Ga. 30662
ATTN: Microbiology Laboratory

5.3.15 Retain one complete set at the Luzenac QA lab at West Windsor, VT for a minimum of 12 weeks.

6.0 OPERATING PROCEDURE:

Loading shall be performed within a covered facility or otherwise protected from dirt, moisture and inclement weather. The loading will be performed by qualified individuals and verified in the log book by the facility supervisor. A loading log sheet is to be filled out and forwarded to Royston, Ga. upon completion of loading.

6.0.1 Inspect all hatches, valves and seals for integrity and compare their numbers either to the cleaning/sanitization log sheet or the seal location log sheet. Top hatch cam locks will be checked only to verify their presence and if they are intact (their seal numbers do not have to be recorded). Any discrepancy is to be reported to the supervisor immediately and before continuing loading procedure. Any discrepancies should also be reported to Royston CPI Quality Services.

6.0.2 Blow off dust collector vent, flexible hose and cover with compressed air.

6.0.3 Perform exterior or mechanical inspection. Do not close/open any valves/gates. If all valves/gates are not securely closed, advise supervisor and do not load until approved by supervisor.

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Document No.: SOPB30

Franchise:

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Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

- 6.0.4 Prior to opening any hatches, open vent valve to relieve any tank pressure in the rail car. Close vent valve.
- 6.0.5 Clean exterior of man way hatch, and spray with IPA and wipe with sterile gauze. Open man way hatch and inspect for moisture, foul odors or particulate contamination. If inspection is unsatisfactory, advise supervisor immediately before continuing loading procedure, and notify Royston Quality Services.
- 6.0.6 If inspection is satisfactory, connect dust collection system which has been previously sanitized with IPA to man way hatch. Wrap hatch cover with a plastic bag to prevent contamination.
- 6.0.7 If loading system has not been utilized in the previous 24 hours, sanitize by injecting approximately 200 ml. of IPA at the exit end of main blower.
- 6.0.8 Clean and sanitize all air and product connections between all talc trailers and delivery system with IPA using sterile gauze.
- 6.0.9 Wipe exterior of delivery hose plug with IPA. Remove and wipe connecting area with IPA. Remove plug from product inlet at bottom of rail car, wipe connecting area with IPA using sterile gauze and then connect delivery hose to rail car.
- 6.0.10 Using the procedure outlined in Section 5.3, set the auto sampler to take the required samples.
- 6.0.11 Open product valve PL4 for ACFX PD 5000 rail cars. Start loading process and continue until trailer #1 is empty. After trailer #1 is empty, close product valve until trailer #2 is ready for unloading. When trailer #2 is ready, open PL4 once again and continue loading process. Continue this procedure until trailers #2, #3, and/or #4 are completely unloaded.

NOTE: The preferred loading procedure is through product valve PL4 for ACFX cars, because it will minimize the probability of clogging the blow down pipe found in compartment #1.

- 6.1 Advise foreman immediately of any dusting during the loading process.
- 6.2 When rail car is completely loaded, allow sufficient time for blower to clear lines. After clearing line, shut down blower and close loading hopper valves.

NOTE the Shut down time.

- 6.3 Shut down dust collector.
- 6.4 Disconnect dust collection pick up cover, and place in proper storage tank and rack. Remove plastic bag from man way hatch. Spray inside of hatch cover and hatch gasket with IPA and wipe with sterile gauze.

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: SOPB30

Franchise:

Location: ROYSTON - QS

Document Type: Permanent

Expiration Date: None

Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

6.5 Remove loading hose and wipe end with IPA. Replace hose cap wiping with IPA using sterile gauze and connect cap to product line.

6.6 Affix J & J or similar type wire seals that have broken, or unreadable seals to locations listed below, and record number on the seal location log sheet (See Exhibit #II).

6.7 Send completed seal location log sheet and required microbial samples to:

J & J Consumer Products Company
P. O. Box 587
545 Old Elbert St.
Royston, Ga. 30662
ATTN: Microbiology Laboratory

7.0 BULK LOADING LOG SHEET

After the rail car has been loaded and all the hatches, valves and caps have been secured, seals must be fastened to all the hatches, valves and caps outlined on the Loading Log: Record of Seal Numbers.

At each location a seal is to be fastened and the number of the seal is recorded next to the location description on the Record of Seal Numbers.

The only exception to recording the seal numbers are for the top hatch cam lock seals. Only the presence and condition of these seals need to be verified.

Seal integrity must be maintained at all times. If seal integrity is not maintained it is cause for rejection.

Seal Locations: See Loading Log: Record of Seal Numbers

Exhibit II is the Luzenac, Inc. hopper car loading sheet.

Send completed sheet and invoice to:

J & J Consumer Product Company
P. O. Box 587
545 Old Elbert St.
Royston, Ga. 30662
ATTN: Microbiology Laboratory

Standard Operating Procedure

Company:

- ☐ Personal Products Worldwide
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- ☐ Johnson & Johnson Products Inc.
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Document No.: SOPB30

Franchise:

Location: ROYSTON - QS

Document Type: Permanent

Expiration Date: None

Subject: INSPECTION, LOADING AND SAMPLING OF PD 5000 RAIL CARS WITH LUZENAC GRADE 66 TALC AT LUDLOW, VT.

EXHIBIT II

LUZENAC AMERICA, Inc.

SEAL LOCATION LOG SHEET

LUDLOW SHIPPING CENTER RAILCAR No: _____ DATE: _____

SEAL LOCATION	SEAL No. (Record)
Man way Hatch #1 (Identified as the hatch nearest to the pressure gauges)	
Man way Hatch #2	
Blowout Port on Hatch #2	
Man way Hatch #3	
Man way Hatch #4	
Blowout Port on Hatch #4	
Man way Hatch #5	
Man way Hatch #6	
Man way Hatch #7	
Man way Hatch #8	
Blow Pipe Cover(On top of railcar)	
Product Inlet #1	
Product Inlet #2	
Air Inlet #1	
Air Inlet #2	
Cleanout Cap (On bottom of railcar)	

Load Identification Numbers:

#1 _____
 #2 _____
 #3 _____
 #4 _____

Sample by _____ Date: _____

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7024

Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
03/08/89	BCR011362	New Test method.
03/21/95	CR020127	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7024

Franchise:
Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

1.0 SCOPE & PURPOSE

This method is applicable to the identification and quantitation of small (typically 1-20 micrometer) asbestiform minerals in powdered talc. Samples may be previously screened with light microscopy or x-ray diffraction techniques.

2.0 PRINCIPLE OF METHOD

The combined techniques of transmission electron microscopy (TEM), selected area electron diffraction (SAED) and energy dispersive x-ray analysis (EDXRA) permit the detection of asbestiform minerals based on morphological characteristics, followed by a definitive mineralogical identification of each fiber.

3.0 INTERFERENCES

Interferences are caused by fibrous particles which must be distinguished from positively identifiable asbestos, and by large particles or particle aggregates which may obscure fibers. Positively identified non-asbestos fibers include rolled talc, ribbon talc, antigorite, silica fibers and iron oxide fibers. Organic additives such as perfumes may crystallize out as fibers or needle-shaped crystals in finished cosmetic products. In the absence of positive identification, all other fibers must be classified as unidentifiable.

4.0 INSTRUMENTAL CONDITIONS

The talc specimen grids are examined in the TEM at an accelerating voltage of 120 kv and at magnification of 20,000X and 5,000X.

5.0 SENSITIVITY

This method is capable of detecting a single fiber as small as 1 micrometer (mm) long by 0.075 mm wide in the entire TEM field, which results in a theoretical detection limit of 10^{-5} weight percent. Such fibers usually can be identified readily by SAED and EDXRA. The mass of a fiber with the above dimensions is 1.1×10^{-14} g for chrysotile and 1.5×10^{-14} g for amphibole.

6.0 LIMIT OF QUANTIFIABLE DETECTION

The detection of five or more asbestiform minerals of one variety in an analysis constitutes a quantifiable level of detection. When no asbestiform minerals are detected, a representative fiber size is used to calculate a detection limit. A representative fiber size is 3 mm long by 0.2 mm wide by 0.06 mm thick, which is considerably larger than the smallest fiber that can be detected (see section 5, SENSITIVITY), but is more typical of small asbestos fibers that are detected in talc analyses. The mass of five such fibers is calculated as follows:

$$\begin{aligned} 3 \text{ mm} \times 0.2 \text{ mm} \times 0.06 \text{ mm} &= 0.036 \text{ mm}^3 \text{ per fiber} \\ \times 3.3\text{E-}12 \text{ g / mm}^3 &= 1.2 \text{ E-}13 \text{ g per fiber} \\ \times 5 \text{ fibers} &= 6\text{E-}13 \text{ grams per 5 fibers.} \end{aligned}$$

Test Method

Company:

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Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

The limit of quantifiable detection for most talc analyses is approximately 6×10^{-4} weight percent. The theoretical and quantifiable detection limits assume homogeneity of the material being sampled.

7.0 QUALITY ASSURANCE

Blank suspensions are routinely prepared and tested in order to monitor potential residual contamination from the sample jars. Blank carbon-coated grids are routinely tested to monitor the ambient fiber count. If greater than 4 fibers per grid are present, the jars are pre-cleaned or new carbon-coated grids are prepared, respective of the test.

8.0 BACKGROUND CORRECTION

As of the time of this writing, background correction has not been necessary. The amount of background asbestos detected has been insignificant in comparison to the levels of asbestos found in contaminated samples.

9.0 PREPARATION AND ANALYSIS TIME

Preparation time per sample (including preparation of related materials) is one hour. Analysis search time per sample is a maximum of two hours.

10.0 APPARATUS

- 10.1 Analytical balance with 0.0001 gram sensitivity
- 10.2 Weighing boats
- 10.3 Narrow spatula
- 10.4 Wide mouth polyethylene jars (125 ml)
- 10.5 Mild ultrasonic bath, minimum 50 watts
- 10.6 Micropipettor (5-10 ml range) with disposable tips
- 10.7 Standard 3 mm diameter, 200 mesh, copper TEM grids, covered with a carbon-coated formvar film.
- 10.8 Transmission electron microscope (TEM) with an 80-120 kv accelerating voltage and energy dispersive x-ray analyzer.

Test Method

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Document No.: TM7024

Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

11.0 REAGENTS

- 11.1 Methyl cellulose, powder, USP 4000 cps - Fisher Certified Reagent #M-352 or equivalent
- 11.2 Water: deionized, particle free (+0.2 mm filtered)
- 11.3 Methyl cellulose solution: 0.002% (wt/vl) (20 ppm). Dissolve 20 % 0.5 mg of methyl cellulose in 500 ml of deionized particle free water to make a 0.004% stock solution. Dilute 1:1 to make a working solution.

NOTE: Methyl cellulose acts as a wetting agent to aid in maintaining a uniform particle distribution as the sample dries, by greatly reducing the surface tension of water.

12.0 SAMPLE PREPARATION

- 12.1 Transfer 30 to 50 mg of talc powder to a clean 125 ml polyethylene jar.
- 12.2 Add 80 ml of 20 ppm methyl cellulose solution, cap and shake vigorously for one minute.
- 12.3 After shaking, loosen cap and ultrasonicate for 10 minutes in order to disperse the finer particles. Then shake again for one minute to produce a uniform suspension.
- 12.4 Immediately after shaking, uncap and remove 9.2 microliters with a micropipette.
- 12.5 Transfer a 9 ml drop to a carbon film covered TEM grid. (Grid was first lightly anchored by 2 parallel strips of double-stick tape mounted 3 mm apart on a clean glass microscope slide.) Repeat to make two sample grids per talc sample.

NOTE: Do not expel the remaining 0.2 ml suspension from the micropipette tip. It tends to sputter and frequently destroys the stability of the sample drop.

- 12.6 Transfer slide with grids to a desiccator. (Drying time is 2-3 hours.) Do not leave the grids on the slide for more than one day as the double-stick tape may adhere too tightly.

NOTE: The talc:water ratio may need to be varied for some samples. Preparation of talc samples with a significantly finer or coarser particle size results in large differences in particle coverage on the TEM grid.

Test Method

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Document No.: TM7024

Franchise:
Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

13.0 TEM ANALYSIS

- 13.1 Definition of fiber: An elongated particle with parallel sides and an aspect ratio K3:1. The definition employed may vary with the needs of the client.
- 13.2 Scan sample at 120-150X magnification to check for even dispersion of particles and to locate grid squares with optimum particle density. (Optimum particle density is particle coverage over 15-35% of the field of view.)
- 13.3 Scan three grid squares on each grid at 20,000X magnification and seven grid squares on each grid at 5,000X for asbestiform minerals. Each asbestiform mineral is recorded as to type (chrysotile, tremolite, anthophyllite, etc.), structure (bundle, clump, fiber) and dimensions (length x width).
- 13.4 Questionable fibers are examined first by SAED. The chrysotile SAED pattern is unique and diagnostic. Amphibole SAED patterns are variable but usually characteristic. Additional analysis and measurement of amphibole SAED patterns are done if warranted.
- 13.5 Ten percent of chrysotile fibers are checked by EDXRA for further confirmation. If the SAED pattern is not clearly diagnostic, or if it is consistent with an amphibole SAED pattern, then it is examined by EDXRA to confirm the identification or to identify the type of amphibole.

14.0 CALCULATION OF RESULTS

- 14.1 Mass of chrysotile fibers: M(f)

$$M(f) = \pi r^2 l \times d$$

$$\pi = 3.14159$$

$$r = \text{fiber radius}$$

$$l = \text{fiber length}$$

$$d = \text{density of chrysotile} = 2.55 \times 10^{-12} \text{ g/mm}^3$$
- 14.2 Mass of asbestiform amphibole particles: M(a)

$$M(a) = l \times w \times th \times d$$

$$l = \text{length}$$

$$w = \text{width}$$

$$th = \text{thickness} \geq 0.3 \text{ width (approximation)}$$

$$d = \text{density of amphiboles} = 3.3 \times 10^{-13} \text{ g/mm}^3$$
- 14.3 Mass of talc deposited on each TEM grid: M(s)

$$M(s) = T \times (V/H)$$

$$T = \text{amount of talc sampled (step 12.1)}$$

$$V = \text{volume of aliquot transferred to TEM grid (step 12.5)}$$

$$H = \text{volume of methyl cellulose solution (step 12.2)}$$

Test Method

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Document No.: TM7024

Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

14.4 Total estimated talc mass examined: $M(t)$

$$M(t) = M(s) \times (N \times A(s)) / A(g)$$

N = number of grid squares examined

$A(s)$ = area of a single TEM grid square

$A(g)$ = area of an entire TEM grid (effective area over which a 9 microliter drop of suspension dries)

14.5 Weight percent:

$$\frac{\text{sum total of } M(f) \text{ or } M(a) \times 100}{M(t)}$$

15.0 CALCULATION OF A DETECTION LIMIT

15.1 $M(dl)$ = A minimum quantifiable mass of asbestos fibers, based on the detection of 5 fibers (approximately $6E-13$ grams, from Section 6).

15.2 Detection Limit (Weight Percent) = $\frac{M(dl) \times 100}{M(t)}$

Test Method

Company:

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Document No.: TM7070

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: FINENESS DETERMINATION OF CERTAIN POWDERS VIA AIR-JET SIEVE

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
05/17/89	BCR011497	New Test method.
03/22/95	CR020134	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7070

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: FINENESS DETERMINATION OF CERTAIN POWDERS VIA AIR-JET SIEVE

1.0 SCOPE & PURPOSE

This method is applicable to the determination of the fineness of certain powders using the air-jet sieve. This method must be referenced in the Product or Material specification prior to use.

2.0 UNUSUAL SAFETY PRECAUTIONS

Handle sieves carefully. A 400 mesh screen costs more than \$100.

3.0 PRINCIPLE OF METHOD

The split nozzle rotates slowly below the sieve. A current of air, produced by the suction of a standard vacuum cleaner type device, blows upwards through a hollow shaft and the slit nozzle to the sieve, and blows the screen free. The particles thus suspended in air (between the sieve cover and the sieve) are separated as the air current circulates. The fine materials are sucked through the screen and into a filter bag by way of the outlet. The coarse materials remain on top of the sieve.

4.0 FUNDAMENTAL EQUATIONS

None.

5.0 INTERFERENCES

Vacuum cleaner device must be cleaned at regular intervals to maintain vacuum at 11 ± 1 " of water.

6.0 PRECISION & ACCURACY

The results of duplicate determinations should not vary by more than 0.5%.

7.0 ANALYSIS TIME

Man Hours (hr.)
Overall Time (hr.)

First sample	0.1	0.1
Each additional sample	0.1	0.1

8.0 APPARATUS

Air-jet sieve with standard vacuum cleaner device.
 200 mm diameter sieve drum with transparent cover.
 Analytical balance
 Tared weighing dish
 1" soft nylon brush
 Manometer

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7070

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: FINENESS DETERMINATION OF CERTAIN POWDERS VIA AIR-JET SIEVE

9.0 REAGENTS

None required.

10.0 STANDARDIZATION

Not applicable.

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

- Step 1. Weigh 10 grams of sample to the nearest 10 mg in a tared weighing dish. (alternate sample sizes may be specified in the Product or Raw Material specification)
- Step 2. Transfer the sample to the sieve drum and cover with the transparent cover.
- Step 3. Place the sieve drum on the air-jet sieve, seat the gasket on the drum against the gasket on the air-jet sieve. Set the timer for 3 minutes. As the air flow starts, again seat the gasket. Adjust the vacuum to 11" of water.
- Step 4. When the unit stops, remove the sieve drum. With the soft brush, brush the material on the transparent cover onto the sieve drum. Brush the surface and edge of the drum so that all material is on one side and can be brushed into the tared weighing dish.
- Step 5. Weigh the material to the nearest 10 mg.

Test Method

Company:

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Document No.: TM7070

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: FINENESS DETERMINATION OF CERTAIN POWDERS VIA AIR-JET SIEVE

13.0 CALCULATIONS for percent passing through sieve

$$P = \frac{W - R}{W} \times 100$$

P = % material passing through the particular sieve

R = Weight of residue remaining on sieve

W = Sample weight

13.1 CALCULATIONS for percent retained on sieve

$$PR = (R / W) \times 100$$

PR = % material retained on the particular sieve

R = Weight of residue remaining on sieve

W = Sample weight

Test Method

Company:

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☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7071

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: COLOR DETERMINATION OF WINDSOR 66 TALC

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
12/02/88	BCR011165	New Test method.
03/22/95	CR020135	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
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☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7071

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: COLOR DETERMINATION OF WINDSOR 66 TALC

1.0 SCOPE & PURPOSE

The purpose of a color determination is to accurately and uniformly measure the color reflectance of cosmetic talc on both the finished product and at various stages in processing.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on the measurement of diffuse green light reflectance.

4.0 FUNDAMENTAL EQUATIONS

Not applicable.

5.0 INTERFERENCES

Samples to be measured must be completely dry as moisture reduces the value of the color reading.

6.0 PRECISION & ACCURACY

The results of duplicate determinations should not vary by more than 0.2 color units.

7.0 ANALYSIS TIME

	<u>Man Hours (hr.)</u>	<u>Overall Time (hr.)</u>
First sample	0.1	0.1
Each additional sample	0.1	0.1

8.0 APPARATUS

- 8.1 Phovolt reflectance and gloss meter
- 8.2 Sample holder
- 8.3 Cleaning tissue
- 8.4 Ethyl alcohol wash bottle

9.0 REAGENTS

Denatured Ethyl Alcohol

10.0 STANDARDIZATION

Zero to black cavity standard then standardize with white enamel plaque.

11.0 SAMPLE PREPARATION

Sample should be thoroughly mixed and dried.

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
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Document No.: TM7071

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: COLOR DETERMINATION OF WINDSOR 66 TALC

12.0 PROCEDURE

- Step 1. Collect sample in a container.
 - Step 2. Fill sample holder and level powder with top of holder.
 - Step 3. Green filter required for reflectance measurement. Check and clean with ethyl alcohol, if dusty.
 - Step 4. Select filter channel G on front panel for green filter.
 - Step 5. Place black cavity standard on the photocell search unit.
 - Step 6. Depress the CHANGE key-the display goes blank.
 - Step 7. Depress the ZERO key-the display reads .0 (± 0.1). If the display does not read between -0.1 and +0.1, repeat steps 5 & 6 again.
 - Step 8. Place the photocell search unit on the white enamel standard plaque.
 - Step 9. Depress the CHANGE key-the display blanks again.
 - Step 10. Depress the STD key-the display will read "75.0" or the last standard value entered for this filter channel. The STD, CHANGE, A, B, and G LEDS will all be lit.
 - Step 11. Enter the white enamel standard plaque value by using the A, B, and G keys to increment the display's digits to the value printed on the back of the plaque in the "Y" scale.
 - Step 12. Depress the STD key again. All LEDS except the selected filter channel LED (G) will go out. This display should now be in the normal display mode and should display the value entered for the white enamel standard plaque (± 0.2). If the display value is incorrect, repeat steps 9 through 10 again.
- **Note:** There is no need to re-enter the white enamel standard plaque value since it is now stored in the memory.
- Step 13. If properly calibrated, the unit is now ready to use for sample measurement.
 - Step 14. Place the photocell search unit over top of the sample holder. LED reading displayed will be the reflectance measurement for the sample presented.
 - Step 15. Remove the photocell search unit from the top of the sample and place it over the white enamel standard plaque. LED readout should return to the standard value unit calibrated to.

13.0 CALCULATIONS

None.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7077

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: CARBONATES IN TALC

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
11/15/78	BCR001434	Test method updated.
03/22/95	CR020138	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7077

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: CARBONATES IN TALC

1.0 SCOPE & PURPOSE

This method is applicable to the rapid determination of carbonates in talc.

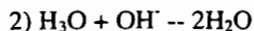
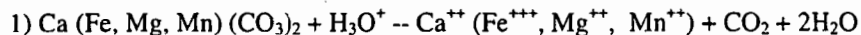
2.0 UNUSUAL SAFETY PRECAUTIONS

Perform the boiling steps in a well-ventilated fume hood.

3.0 PRINCIPLE OF METHOD

The method is based on reaction and solution of the carbonates with hydrochloric acid resulting in the evolution of carbon dioxide. The excess acid is titrated with standard sodium hydroxide.

4.0 FUNDAMENTAL EQUATIONS



5.0 INTERFERENCES

None.

6.0 SENSITIVITY

Not applicable.

7.0 ANALYSIS TIME

Man-hours (hr.)
Overall Time (hr.)

First sample

0.4

0.4

Each additional sample

0.4

0.4

8.0 APPARATUS

Erlenmeyer flasks, 250 ml capacity

Pipette, 50 ml capacity

Graduated cylinder, 25 ml capacity

Burette, 50 ml capacity

Tongs

Interval timer (Gilbert, Fisher Cat. No. 6-660 or equivalent)

Hot plates: Two are required. The first (for example, a type similar to the "Ful-Kontrol") must have the capacity to bring the sample to a boil in less than two minutes. The second should be set to maintain a moderate boil for ten minutes.

Test Method

Company:

- ☐ Personal Products Worldwide
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☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7077**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** CARBONATES IN TALC**9.0 REAGENTS****9.1 Alcohol, 3A****9.2 Hydrochloric Acid, approximately 0.1N**

Dilute an acculute to 1 liter and pipette 50 ml of this solution into an Erlenmeyer flask and titrate with 0.1000N sodium hydroxide to the methyl red end point. If more than 50.00 ml of the sodium hydroxide is required to obtain the end point, add distilled water to the mark and mix well. Test another 50.00 ml portion of the acid. Continue this alternate diluting and testing until 50.00 ml of acid requires less than 50.00 ml of sodium hydroxide to neutralize.

9.3 Sodium Hydroxide, 0.1000N

Acculute or equivalent.

9.4 Indicator Solution - Methyl Red, 0.1%

Dissolve 100 mg of methyl red in 100 ml of alcohol and filter if necessary.

10.0 STANDARDIZATION

Not applicable.

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

Step 1. Weigh a 5.000 g sample of talc to the nearest milligram into a 250-ml Erlenmeyer flask.

Step 2. Add 25.0 ml of denatured alcohol to the sample and swirl the flask until the talc is dispersed.

Step 3. Pipette 50.00 ml of 0.1N hydrochloric acid into the flask and swirl the contents.

Step 4. Bring the contents of the flask to a boil as rapidly as possible (less than 2 minutes) on the first hot plate, then transfer the flask to the second hot plate.

Step 5. Immediately set the timer for 10 minutes and allow the contents of the flask to boil moderately for 10 minutes.

Step 6. At the end of the time interval, transfer the flask to an ice-water bath. Swirl the flask in the bath to aid in cooling it as rapidly as possible.

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

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Document No.: TM7077

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: CARBONATES IN TALC

Step 7. When the contents of the flask are cooled to room temperature, add 2 ml of methyl orange indicator to the flask.

Step 8. Titrate the excess hydrochloric acid with 0.1N sodium hydroxide to the yellow end point.

Step 9. Determine the blank value by adding 25.0 ml of denatured alcohol and 50.00 ml of 0.1N hydrochloric acid to a clean 250-ml Erlenmeyer flask and carry this flask through the procedure (Steps 4 through 8).

13.0 CALCULATIONS

$$C = \frac{(B - S) \times N \times 0.04217}{W} \times 100$$

C = Percent carbonates as $MgCO_3$

B = Volume of standard sodium hydroxide to titrate blank (ml)

S = Volume of standard sodium hydroxide to titrate sample (ml)

N = Normality of standard sodium hydroxide

W = Sample weight (g)

0.04217 = Milliequivalent weight of magnesium carbonate (g per meq.)

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7164

Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: LOSS ON DRYING (OVEN - 105°C)

REVISION	AUTHORIZATION	DESCRIPTION OF CHANGE
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05/09/79	BCR001813	New Test method.
03/23/95	CR020175	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7164**Franchise:****Location:** ROYSTON, FLUID, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** LOSS ON DRYING (OVEN - 105°C)

1.0 SCOPE & PURPOSE

This method is applicable to the determination of any substance which will volatilize at the specified temperature. Very often prior knowledge of the sample allows the assumption that the volatilized substance is a single compound, e.g., water.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on the volatilization of moisture and/or other components when the sample is heated and subsequent determination of the loss of weight.

4.0 FUNDAMENTAL EQUATIONS

None.

5.0 INTERFERENCES

Care must be taken to protect the sample from sudden drafts, particularly since the material is very light and fluffy.

6.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 0.08% absolute.

7.0 ANALYSIS TIME

Man-Hours (hrs.)Overall Time (hrs.)

First sample

0.2

0.2

Each additional sample

0.2

0.2

8.0 APPARATUS

Weighing bottles, low form with ground glass stoppers.

9.0 REAGENTS

No special reagents required.

10.0 STANDARDIZATION

Not applicable.

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7164

Franchise:

Location: ROYSTON, FLUID, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: LOSS ON DRYING (OVEN - 105°C)

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

Step 1. Weigh approximately 2 grams of sample to the nearest 0.1 mg into a tared weighing bottle and dry to constant weight in an oven at 105°C with the stopper resting open at an angle of 30°C.

Step 2. Remove the bottle from the oven after carefully replacing the stopper, cool to room temperature in a desiccator and weigh to the nearest 0.1 mg.

13.0 CALCULATIONS

$$L = \frac{W - R}{W} \times 100$$

L = % loss on drying

R = Weight of dried residue (grams)

W = Sample weight (grams)

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7165

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: SOLUBILITY IN ACID (TALC)

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
05/09/79	BCR001813	New Test method.
12/21/92	CR015062	Sec. 12.2, acid stirring reference added. (J. Payeur)
03/23/95	CR020176	Location revised. Product page deleted. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7165**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** SOLUBILITY IN ACID (TALC)

1.0 SCOPE & PURPOSE

This method is applicable to the determination of the concentration in talc of materials soluble in diluted hydrochloric acid.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on heating the sample with diluted hydrochloric acid, filtering the insoluble residue, and calculating the soluble material by difference.

4.0 FUNDAMENTAL EQUATIONS

None.

5.0 INTERFERENCES

None.

6.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 0.2% absolute.

7.0 ANALYSIS TIME

Man-Hours (hr.)Overall Time (hrs.)

First sample

0.3

3.0

Each additional sample

0.3

0.3

8.0 APPARATUS

Porcelain Gooch Crucible: No. 3 size

Glass Fiber Filter Matts: To fit No. 3 crucible

9.0 REAGENTS

Hydrochloric Acid Solution: Mix 236 mL of concentrated hydrochloric acid with sufficient purified water to make 1000 mL.

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7165

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: SOLUBILITY IN ACID (TALC)

10.0 STANDARDIZATION

Not applicable.

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

- 12.1 Weigh approximately 2 g of sample to the nearest 1 mg into a 150 mL beaker.
- 12.2 Add 50 mL of hydrochloric acid solution, cover the beaker with a watch glass, and heat on a steam bath for 30 minutes. The acid must be added while stirring slowly to make sure all particles are completely wetted.
- 12.3 Filter the undissolved residue through a tared Gooch crucible. Transfer all the residue to the crucible with the aid of a stream of hot purified water.
- 12.4 Wash the residue free of acid with hot purified water.
- 12.5 Transfer the crucible to an oven at 105°C and dry to constant weight.

13.0 CALCULATIONS

$$S = \frac{W - R}{W} \times 100$$

where:

S = Percent material soluble in acid
R = Weight of insoluble residue - g
W = Sample weight - g

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
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Document No.: TM7166

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: BULK DENSITY (POWDERS)

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
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11/13/80	BCR002822	New Test method.
03/23/95	CR020177	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7166

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: BULK DENSITY (POWDERS)

1.0 SCOPE & PURPOSE

This method determines the bulk density of loose dry powders with the Scott Volumeter.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

A unit size container is filled with the dry powder in such a way that the powder is loose and not packed.

4.0 FUNDAMENTAL EQUATIONS

None.

5.0 INTERFERENCES

Any vibrations will cause settling of the powder. Special care should be taken that the bench is not hit or that doors are not slammed.

6.0 PRECISION & ACCURACY

Results of duplicate determinations should be within .02 grams.

7.0 ANALYSIS TIME

Man-Hours (hrs.)

Overall Time (hrs.)

First sample	0.1	0.1
Each additional sample	0.1	0.1

8.0 APPARATUS

- 8.1 Scott Volumeter equipped with a 16 mesh screen, brass funnels, baffle box, and appropriate stand and base
- 8.2 Tared density cup, one inch cube with a capacity of 1.000 cubic inch (+ 0.0002 cu. in.)
- 8.3 Spatula, stainless steel, 1/2 inch wide
- 8.4 Brush, stiff, 1 inch wide
- 8.5 Analytical balance
- 8.6 Brush, soft, 1 inch wide

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7166

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: BULK DENSITY (POWDERS)

9.0 REAGENTS

None required.

10.0 STANDARDIZATION

Not applicable.

11.0 SAMPLE PREPARATION

None required.

12.0 PROCEDURE

Step 1. Place several spatula-fulls of powder on the screen.

Step 2. With a stiff brush, gently brush the powder on the screen so that it flows down through the baffle box.

Step 3. As the powder starts to flow gently slide the cube under the bottom funnel. Allow the powder to flow only until it completely fills and overflows on all sides and corners of the cup.

Step 4. Remove the excess powder by passing a spatula across the top of the cup, moving it parallel to and in contact with the cup, and along a diagonal of the cup. Keep the blade flat and level, using it to cut off rather than push aside the excess powder. Pass the spatula back and forth until all excess powder has been removed.

NOTE: If there are any unfilled areas on the surface of the powder, the test should be voided.

Step 5. Settle the powder in the cup by tapping the cup with the wooden spatula handle.

Step 6. Weigh the cup and sample to the nearest 0.01 gram.

Step 7. Repeat Steps 1 to 6 ten times and calculate the average of the ten aliquot weights.

13.0 CALCULATIONS

Subtract the weight of the cube from the average total weight. This gives bulk density in grams per cubic inch. Convert this value to pounds per cubic feet by referring to the attached chart.

For lighter or heavier materials:

gram per cubic inch x 3.81 = lb. per cubic feet

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7166

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: BULK DENSITY (POWDERS)

CONVERSION CHART FORM GRAMS TO CUBIC FOOT POUNDS

5.01	19.09	5.41	20.61	5.81	22.14	6.21	23.66	6.61	25.18
5.02	19.13	5.42	20.65	5.82	22.17	6.22	23.70	6.62	25.22
5.03	19.16	5.43	20.69	5.83	22.21	6.23	23.74	6.63	25.26
5.04	19.20	5.44	20.73	5.84	22.25	6.24	23.77	6.64	25.30
5.05	19.24	5.45	20.76	5.85	22.29	6.25	23.81	6.65	25.34
5.06	19.28	5.46	20.80	5.86	22.33	6.26	23.85	6.66	25.37
5.07	19.32	5.47	20.84	5.87	22.36	6.27	23.89	6.67	25.41
5.08	19.35	5.48	20.88	5.88	22.40	6.28	23.93	6.68	25.45
5.09	19.39	5.49	20.92	5.89	22.44	6.29	23.96	6.69	25.49
5.10	19.43	5.50	20.96	5.90	22.48	6.30	24.00	6.70	25.53
5.11	19.47	5.51	20.99	5.91	22.52	6.31	24.04	6.71	25.57
5.12	19.51	5.52	21.03	5.92	22.56	6.32	24.08	6.72	25.60
5.13	19.55	5.53	21.07	5.93	22.59	6.33	24.12	6.73	25.64
5.14	19.58	5.54	21.11	5.94	22.63	6.34	24.16	6.74	25.68
5.15	19.62	5.55	21.15	5.95	22.67	6.35	24.19	6.75	25.72
5.16	19.66	5.56	21.18	5.96	22.71	6.36	24.23	6.76	25.76
5.17	19.70	5.57	21.22	5.97	22.75	6.37	24.27	6.77	25.79
5.18	19.74	5.58	21.26	5.98	22.78	6.38	24.31	6.78	25.83
5.19	19.77	5.59	21.30	5.99	22.82	6.39	24.35	6.79	25.87
5.20	19.81	5.60	21.34	6.00	22.86	6.40	24.38	6.80	25.91
5.21	19.85	5.61	21.37	6.01	22.90	6.41	24.42	6.81	25.95
5.22	19.89	5.62	21.41	6.02	22.94	6.42	24.46	6.82	25.98
5.23	19.93	5.63	21.45	6.03	22.97	6.43	24.50	6.83	26.02
5.24	19.96	5.64	21.49	6.04	23.01	6.44	24.54	6.84	26.06
5.25	20.00	5.65	21.53	6.05	23.05	6.45	24.57	6.85	26.10
5.26	20.04	5.66	21.56	6.06	23.09	6.46	24.61	6.86	26.14
5.27	20.08	5.67	21.60	6.07	23.13	6.47	24.65	6.87	26.17
5.28	20.12	5.68	21.64	6.08	23.16	6.48	24.69	6.88	26.21
5.29	20.15	5.69	21.68	6.09	23.20	6.49	24.73	6.89	26.25
5.30	20.19	5.70	21.72	6.10	23.24	6.50	24.77	6.90	26.29
5.31	20.23	5.71	21.76	6.11	23.28	6.51	24.80	6.91	26.33
5.32	20.27	5.72	21.79	6.12	23.32	6.52	24.84	6.92	26.37
5.33	20.31	5.73	21.83	6.13	23.36	6.53	24.88	6.93	26.40
5.34	20.35	5.74	21.87	6.14	23.39	6.54	24.92	6.94	26.44
5.35	20.38	5.75	21.91	6.15	23.43	6.55	24.96	6.95	26.48
5.36	20.42	5.76	21.95	6.16	23.47	6.56	25.00	6.96	26.52
5.37	20.46	5.77	21.98	6.17	23.51	6.57	25.03	6.97	26.56
5.38	20.50	5.78	22.02	6.18	23.55	6.58	25.07	6.98	26.59
5.39	20.54	5.79	22.06	6.19	23.58	6.59	25.11	6.99	26.63
5.40	20.57	5.80	22.10	6.20	23.62	6.60	25.15	7.00	26.67

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7167

Franchise: Adult/Kids/Baby

Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: FINENESS (SIEVE ANALYSIS)

REVISION	AUTHORIZATION	DESCRIPTION OF CHANGE
09/07/84	BCR007209	New Test method.
03/23/95	CR020178	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)
12/05/00	CR225134	Location revised to add NBP. (S. Vass)(732-422-6252) LPC deleted as a location. (SPEC. DEPT.)

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7167

Franchise: Adult/Kids/Baby

Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

Subject: FINENESS (SIEVE ANALYSIS)

1.0 SCOPE & PURPOSE

This method is applicable to the determination of the fineness of powders utilizing standard sieves.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on the determination of the weight of residue remaining on a standard sieve after the sample has been shaken through the screen. The results are calculated as percent passing through the sieve.

4.0 INTERFERENCES

None.

5.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 0.5% absolute.

6.0 ANALYSIS TIME

Man-Hours (hr.)

Overall Time (hr.)

First Sample	0.3	0.8
Each Additional Sample	0.3	0.3

7.0 APPARATUS

Mechanical Sieve Shaker: W.S. Tyler RO-TAP or equivalent
 Standard Sieves: Meeting the requirement of ASTM E-11; 60, 100 and 200 mesh
 Sieve Cover and Pan Bottom
 Sieve Separator Bottom
 Brush, Camel's Hair, 1"

8.0 REAGENTS

No special reagents required.

9.0 STANDARDIZATION

Not applicable.

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7167

Franchise: Adult/Kids/Baby

Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

Subject: FINENESS (SIEVE ANALYSIS)

10.0 SAMPLE PREPARATION

Not applicable.

11.0 PROCEDURE

Step 1. Assemble a pan bottom and sieve(s) No. 60, 100 and 200 in order of increasing NBS number, from top to bottom of the nest.

Step 2. Weigh approximately 50 g of sample to the nearest 10 mg into the top sieve and close with a sieve cover.

Step 3. Add the RO-TAP lid to the nest, place the assembly in the RO-TAP and shake for 30 minutes.

Step 4. Starting with the upper most (60 mesh) sieve, brush adhering sample from the sieve cover, the upper sieve and the sides of the sieve onto the residue using a camel's hair brush. Brush the residue on the sieve for two minutes collecting what passes through on the next lowest sieve. Repeat for each sieve.

Step 5. Carefully transfer the residue remaining on each sieve to a tared weighing paper or watch glass and weigh to the nearest 1 mg.

12.0 CALCULATIONS

$$P_1 = \frac{W - R_1}{W} \times 100$$

$$P_2 = \frac{W - (R_1 + R_2)}{W} \times 100$$

$$P_3 = \frac{W - (R_1 + R_2 + R_3)}{W} \times 100$$

Where:

$P_1, P_2, P_3 =$ Percent material passing through the 1st, 2nd, and 3rd screens, respectively.

$R_1, R_2, R_3 =$ Weight of residue remaining on 1st, 2nd, and 3rd screens, respectively, in grams
 $W =$ Sample Weight, in grams

13.0 REFERENCES

CPI Notebook 736, page 29 (MFV)
CPI Notebook 894, page 17 (JP)

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7168

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: HEAVY METALS

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
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11/13/80	BCR002821	New Test method.
03/23/95	CR020179	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7168**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** HEAVY METALS

1.0 SCOPE & PURPOSE

This method is applicable to the determination of 1 to 50 ppm of metallic impurities which form colored precipitates with hydrogen sulfide.

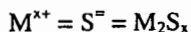
2.0 UNUSUAL SAFETY PRECAUTIONS

Hydrogen Sulfide is extremely toxic. Perform this test in a fume hood.

3.0 PRINCIPLE OF METHOD

This method is based on the precipitation of insoluble metallic sulfides in a weak acid solution. Lead, bismuth, copper, cadmium, mercury, antimony, and tin will precipitate to a greater or less extent under the conditions of the test. The quantity of precipitate is estimated visually by comparing with a series of lead standards and the results are reported in terms of the parts of lead per million parts of test sample.

4.0 FUNDAMENTAL EQUATIONS



5.0 INTERFERENCES

In order to reproduce the precipitation as closely as possible, the analyst should control the acid concentration carefully, since the solubility of each of the heavy metal sulfides varies with pH. The appearance of a white precipitate indicates the presence of either an oxidizing agent, which oxidizes hydrogen sulfide to colloidal sulfur, or relatively high concentrations of zinc or aluminum, which precipitate as zinc sulfide and aluminum hydroxide, respectively.

6.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 5 ppm of heavy metals as lead.

7.0 ANALYSIS TIME

First sample
Each additional sample

8.0 APPARATUS

Nessler Tubes: 50 ml, matched set of six
Nessler Tube Rack

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7168**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** HEAVY METALS

9.0 REAGENTS

- 9.1 Saturated Hydrogen Sulfide Solution: Bubble hydrogen sulfide gas into purified water for 5-10 minutes. Test the solution as follows: Add a few mls. of the solution to a few mls. of fresh 10% ferric chloride solution. The appearance of a voluminous white precipitate of sulfur indicates that the hydrogen sulfide solution is saturated. Prepare this solution fresh as needed.
- 9.2 Stock Lead Solution: Weigh exactly 0.1598 g of lead nitrate into a one liter volumetric flask. Add 100 ml of purified water containing 1.0 ml of concentrated nitric acid and dissolve the salt. Dilute to the mark with purified water and mix. Store this solution in a polyethylene bottle. (1 ml = 0.1 mg of Pb).
- 9.3 Standard Lead Solution: Pipet 10.0 ml of lead stock solution into a one liter volumetric flask. Dilute to one liter with purified water and mix well. (1 ml = 1 mcg. of Pb). Prepare this solution fresh as needed.
- 9.4 Hydroxylamine Hydrochloric Solution: Prepare a saturated solution of hydroxylamine hydrochloride in purified water.

10.0 STANDARDIZATION

NOTE: The standardization must be performed as directed in Section 12.

11.0 SAMPLE PREPARATION

- Step 1. Weigh 10.00 ± 0.01 g of sample into a 250 ml beaker.
- Step 2. Add 50 ml of 0.5 N hydrochloric acid and bring to a boil on a hot plate.
- Step 3. Boil gently for 15 minutes, taking care that the mixture does not foam excessively. Stir the mixture intermittently with a glass stirring rod to return the sample to the liquid phase.
- Step 4. Cool the mixture and allow it to settle.
- Step 5. Decant the supernatant liquid through a filter paper into a 100 ml volumetric flask, retaining as much insoluble material in the beaker as possible. Add 10 ml of hot purified water to the beaker, stir, let settle and decant through the same paper into the same flask.
- Step 6. Repeat the washing twice more.
- Step 7. Wash the filter paper with 10-15 ml of hot purified water into the flask. Cool to room temperature and dilute to the mark with purified water and mix.

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7168

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: HEAVY METALS

12.0 PROCEDURE

Step 1. Pipette 10.0 ml of the sample preparation into a 50 ml beaker.

Step 2. Using a pH meter, adjust the pH of the sample preparation to 3.0 - 3.5 with sodium hydroxide solution, taking care that the pH does not go above 4.0.

NOTE: Use 5N sodium hydroxide until a pH of 2.0 - 2.5 is attained, and 0.1N sodium hydroxide to a pH of 3.0 - 3.5.

Step 3. Prepare a standard by pipetting 10.0 ml of standard lead solution into a 50 ml beaker. Adjust the pH of the solution to 3.0 - 3.5 as directed above.

Step 4. Add glass beads to the beakers and heat the solutions to boiling.

Step 5. Add hydroxylamine hydrochloride solution to the sample beaker in 5 drop increments, allowing the solution to boil one minute after the addition of each increment, until the yellow color of the ferric iron has disappeared and the solution becomes colorless.

Step 6. Add the same quantity of hydroxylamine hydrochloride solution to the standard and transfer the sample and standard solution to 50 ml Nessler tubes. Wash the beakers with small portions of purified water to a total volume of 40 ml, and cool the tubes rapidly to room temperature.

Step 7. Add 10 ml of saturated hydrogen sulfide solution, 1.0 g of 1 absorbic acid and dilute to the mark with purified water.

Step 8. Mix the tubes by inversion until the absorbic acid has dissolved.

Step 9. Let the tubes stand for 5 minutes and compare the colors.

13.0 CONCLUSIONS

If the color of the sample solution is lighter than that of the standard solution, the sample contains less than 10 ppm of heavy metals as lead.

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7169

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: ARSENIC CONTENT (TALC)

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
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09/05/90	CR012280	New Test method.
03/23/95	CR020180	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7169

Franchise:
Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ARSENIC CONTENT (TALC)

1.0 SCOPE & PURPOSE

This method is applicable to the determination of from 1 to 10 micrograms of arsenic in water or acid soluble substances.

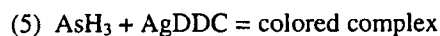
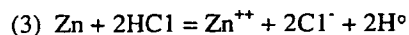
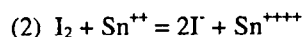
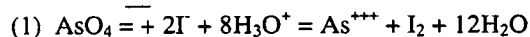
2.0 UNUSUAL SAFETY PRECAUTIONS

Do not pipette the absorber solution by mouth; use a rubber pipette bulb.

3.0 PRINCIPLE OF METHOD

The method is based on the evolution of arsine (AsH_3) from an acid solution and its subsequent absorption in and reaction with a solution of silver diethyldithiocarbamate to form a colored complex. The arsenic, in the form of arsenate, is extracted from the talc with acid and reduced to arsenite by the action of iodide ion in the presence of stannous ion (1,2). The arsenious ion is reduced to arsine with nascent hydrogen (3,4) and is swept into a solution of silver diethyldithiocarbamate, with which it forms a red complex (5).

4.0 FUNDAMENTAL EQUATIONS



5.0 INTERFERENCES

Certain metals, among which are copper, nickel and cobalt, interfere with the evolution of arsine. Compounds which liberate hydrogen sulfide under the conditions of the test interfere. Small amounts of hydrogen sulfide are removed with a lead sulfide impregnated cotton or glass wool, but larger amounts should be treated as in USP XVII under arsenic test.

6.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 0.5 ppm of arsenic.

7.0 ANALYSIS TIME

Man-Hours (hrs.)
Overall Time (hrs.)

First sample	0.75	1.50
Each additional sample	0.25	0.25

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7169**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** ARSENIC CONTENT (TALC)

8.0 APPARATUS

Arsenic Generator - Absorber Apparatus: This apparatus is based on recommendations of the American Conference of Government Industrial Hygienists and is available from Fisher Scientific Company. At least three of these are required.

9.0 REAGENTS

- 9.1 Absorber Solution: Dissolve 0.500 g of silver diethyldithiocarbamate in pyridine and dilute to 100 ml with pyridine in a volumetric flask. This reagent is stable if stored in an amber glass bottle.
- 9.2 Stannous Chloride Solution: Dissolve 40 g of stannous chloride dihydrate in 100 ml of concentrated hydrochloric acid.
- 9.3 Zinc Granular 20 Mesh Reagent Grade; Low in Arsenic, Merck Reagent Grade: Zinc purchased from other suppliers may have a different surface area, which will effect the rate of evolution of hydrogen and consequently, the results. Suspected lots should be compared to the Merck Reagent Grade.
- 9.4 Potassium Iodine Solution: Dissolve 15 g of potassium iodide in 100 ml of purified water. Prepare this solution fresh as needed.
- 9.5 Lead Acetate Wool: Dissolve 10 g of lead acetate in 100 ml of purified water. Saturate a portion of cotton or glass wool with this solution, drain and dry. Store in a tightly capped jar.
- 9.6 Stock Arsenic Solution: Dissolve 0.132 g of arsenic trioxide in 5 ml of 5 N sodium hydroxide in a small flask. Neutralize this solution to phenolphthalein with 5 N sulfuric acid and add 10 ml more of 5 N sulfuric acid. Transfer the solution quantitatively to a liter volumetric flask, dilute to the mark with recently boiled and cooled purified water and mix. (1 ml = 0.1 mg arsenic).
- 9.7 Standard Arsenic Solution: Pipette 1.00 ml of stock arsenic solution into a 100 ml volumetric flask, dilute to the mark with purified water and mix. (1 ml = 1 mcg). Prepare this solution fresh as needed.

10.0 STANDARDIZATION

For standardization, Cf. Section 12, PROCEDURE.

11.0 SAMPLE PREPARATION

- Step 1. Weigh 10.00 ± 0.01 g of sample into a 250 ml beaker.
- Step 2. Add 50 ml of 0.5 N hydrochloric acid and bring to a boil on a hot plate.
- Step 3. Boil gently for 15 minutes, taking care that the mixture does not foam excessively. Stir the mixture intermittently with a glass stirring rod to return sample to the liquid phase.

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7169**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** ARSENIC CONTENT (TALC)

Step 4. Cool the mixture and allow it to settle.

Step 5. Decant the supernatant liquid through a filter paper into a 100 ml volumetric flask, retaining as much insoluble material in the beaker as possible. Add 10 ml of hot purified water to the beaker, stir, let settle and decant through the same paper into the same flask.

Step 6. Repeat the washing twice more.

Step 7. Wash the filter paper with 10 - 15 ml of hot purified water into the flask. Cool to room temperature and dilute to the mark with purified water and mix.

12.0 PROCEDURE

Step 1. Pipette 20.0 ml of the sample preparation into the reaction flask of an arsenic generator absorber apparatus.

Step 2. Dilute the sample preparation to 50 ml with purified water. Place 50 ml of purified water in another flask as a reagent blank.

Step 3. Pipette 5.0 ml of standard arsenic solution into a third flask and dilute to 50 ml with purified water.

Step 4. Place a plug of lead acetate wool into each scrubber unit. Lubricate all joints with silicone stopcock grease and connect the scrubber units to the absorbers.

Step 5. To each flask add 2 ml of potassium iodide solution, 8 ml of concentrated hydrochloric acid and 0.5 ml of stannous chloride solution.

Step 6. Swirl the flasks, cover with small beakers and heat on a steam bath for 5 minutes.

Step 7. Remove the flasks from the steam bath, and cool in an ice bath for approximately 10 minutes. While the samples are cooling, pipette 5.0 ml of absorber solution into each absorber.

Step 8. Add 6.0 g of granular zinc to one flask and immediately connect an absorber scrubber unit.

Step 9. Repeat this operation for the other flasks.

Step 10. Allow the reaction to continue for 30 minutes, then warm the flasks gently by immersing in 40 - 50°C water for 15 minutes.

Step 11. Transfer the absorber solutions to clean, dry 1 cm Pyrex cuvettes.

Step 12. Measure the absorbance of the sample and standard versus the reagent blank at a wavelength of 540 mμ in a spectrophotometer or in a filter photometer using a 525 mμ filter.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
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☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7169

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: ARSENIC CONTENT (TALC)

13.0 CONCLUSIONS

If the absorbance of the sample is less than or greater than the absorbance of the standard, the sample contains less than or more than 2.5 ppm arsenic, respectively. If the absorbance of the sample is equal to the absorbance of the standard, the sample contains 2.5 ppm arsenic.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7170

Franchise:

Location: ROYSTON, LPC, ORTHO-
MCNEIL, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: COLOR

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
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05/09/79	BCR001813	New Test method.
03/23/95	CR020181	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7170**Franchise:****Location:** ROYSTON, LPC, ORTHO-MCNEIL, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** COLOR**1.0 SCOPE & PURPOSE**

This method is applicable to the qualitative determination of the color of various materials.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on the visual comparison of the sample with a suitable standard.

4.0 FUNDAMENTAL EQUATIONS

None.

5.0 INTERFERENCES

None.

6.0 SENSITIVITY

Not applicable.

7.0 ANALYSIS TIME**Man-Hours (hrs.)****Overall Time (hrs.)**

First sample

0.1

0.1

Each additional sample

0.1

0.1

8.0 APPARATUS

No special apparatus required.

9.0 REAGENTS

Standard Material - Available from Quality Control Department.

10.0 STANDARDIZATION

Not applicable.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7170

Franchise:

Location: ROYSTON, LPC, ORTHO-
MCNEIL, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: COLOR

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

Compare the sample and the standard visually.

13.0 CONCLUSIONS

If the sample is as white as or whiter than the standard, it shall pass the test.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7171

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: SOLUBILITY IN ACID (MAGNESIUM CARBONATE TITRATION)

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
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05/10/79	BCR001813	New Test method.
03/23/95	CR020182	Location revised. (Spec. Dept.)
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7171

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: SOLUBILITY IN ACID (MAGNESIUM CARBONATE TITRATION)

1.0 SCOPE & PURPOSE

This method is applicable to the determination of acid solubility of talc.

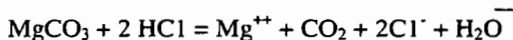
2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The method is based on the reaction of alkaline materials in the talc with excess acid (1). At the end of the reaction period, the excess is back-titrated with standard sodium hydroxide (2) and the acid soluble material calculated as magnesium carbonate:

4.0 FUNDAMENTAL EQUATIONS



5.0 INTERFERENCES

Since this method is empirical in nature, the reaction time should be strictly adhered to.

6.0 PRECISION & ACCURACY

Typical Results: The difference between results of duplicate determinations should not exceed 0.1% absolute.

7.0 ANALYSIS TIME

Man-Hours (hrs.)

Overall Time (hrs.)

First sample

0.3

1.0

Each additional sample

0.2

0.2

8.0 APPARATUS

No special apparatus required.

9.0 REAGENTS

No special reagents required.

10.0 STANDARDIZATION

Not applicable.

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7171

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: SOLUBILITY IN ACID (MAGNESIUM CARBONATE TITRATION)

11.0 SAMPLE PREPARATION

Not applicable.

12.0 PROCEDURE

- Step 1. Weigh approximately 5 g of sample to the nearest 1 mg into a 250 ml Erlenmeyer flask.
- Step 2. Add 50.0 ml of 0.2 N hydrochloric acid and swirl to wet and disperse the sample.
- Step 3. Heat the mixture to 120°F in a forced air or convection oven for 45 minutes with occasional shaking.
- Step 4. Heat the mixture to boiling for 10 seconds to expel carbon dioxide. Use care that it does not boil over.
- Step 5. Cool to room temperature, add 8 drops of methyl orange indicator solution, and titrate with standard 0.2 N sodium hydroxide to a yellow end point.
- Step 6. Perform duplicate blank determinations, omitting the heating step.

13.0 CALCULATIONS

$$A = \frac{(B - S) \times N \times 0.04217}{W} \times 100$$

- A = Percent acid soluble, calculated as magnesium carbonate
- B = Volume of standard 0.2 N sodium hydroxide to titrate blank - ml
- S = Volume of standard 0.2 N sodium hydroxide to titrate sample - ml
- W = Sample weight - g

0.04217 = Milliequivalent weight of magnesium carbonate - g per meq.

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7252**Franchise:****Location:** ALL APPLICABLE**Document Type:** Permanent**Expiration Date:** None**CONFIDENTIAL****Subject:** VISUAL

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
07/24/89	BCR011556	Test method updated.
03/28/95	CR020411	Sec. 5.2 added. BPC changed to CPC in Secs. 11.0 and 12.2. Temperature range expanded from 20°C - 25°C to 20°C - 30°C in Sec. 12.1. (CA. Hoffman) (908-874-1394)
07/28/95	CR021660	Section 8.0 revised to read "If applicable" at the finish of the statement. Section 12.3, Appearance of Non-Formulated Products added. (J. Fonseca/ M.Santos)(809-733-8220-3257)
07/14/97	CR028316	Added NDA statement to page 1 to assure Regulatory Affairs approval of all changes made to test method. Updated company name throughout document. (G. Ferko) (908-874-1824)
02/08/99	CR033914	"NDA" statement deleted from cover page. (Spec. Dept.)(908-874-1474)

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7252

Franchise:
Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

Subject: VISUAL

1.0 SCOPE & PURPOSE

This method is applicable to the simple psychosensory evaluation (i.e., appearance) of materials or products.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

The test sample is compared to a standard sample or written description for the characteristic.

4.0 EQUATIONS

None.

5.0 INTERFERENCES

5.1 Area should be suitably lighted.

5.2 When comparing samples against approved visual standards, a standard light source shall be used.

6.0 ACCURACY

Not determined.

7.0 ANALYSIS TIME

Man-Hours (Hrs.)

Overall Time (Hrs.)

First Sample	.05	.05
Second Sample	.05	.05

8.0 APPARATUS

Glass plate, approximately 3" x 6", or equivalent Spatula, 5" blade, or equivalent (If applicable).

9.0 REAGENTS

None.

10.0 STANDARDIZATION

None.

Test Method

Company:

☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7252

Franchise:
Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

Subject: VISUAL

11.0 SAMPLE PREPARATION

Refer to the material or product specification for any special instructions. If the sample is an initial receipt, with no previously accepted lot available, check with CPC Product Development, Quality Services or Technical Service to establish a standard.

12.0 PROCEDURE

12.1 APPEARANCE OF RAW MATERIALS

The sample must be examined carefully to ensure that it meets the requirements of the specification. The physical state, color, and if appropriate, shape should be noted. Examine the sample for the presence of any foreign matter. Observations for color or clarity of liquids should be done in clear, colorless bottles. If the sample is unexpectedly turbid, check that it is at the temperature designated in the specification. If no temperature is specified, observations should be made at room temperature (20° to 30°C).

12.2 APPEARANCE OF FORMULATED PRODUCTS (BULK & FINISHED PRODUCT)

The sample must be examined carefully and, if required, compared to a standard to ensure that it conforms to the specification. The physical state and color should be noted. Products should be uniform, free of lumps, particulates and foreign matter. Observations for color and clarity of liquid products should be made in a clear, colorless container. Make note of any separation or nonhomogeneity.

Unless otherwise stated in the specification, finished products should be dispensed according to label instructions. In general, products which may separate on standing (lotions, No More Tangles, etc.) should be mixed before sampling. Products which do not normally separate (creams, sticks, gels, clear shampoos, etc.) should be sampled without mixing. For emulsions such as creams and lotions, spread at least a 5 gram portion of the product on a 6" x 6" glass plate using a weighing spatula. Examine the resulting film over both a light and dark background and make note of any lumps or streaks. Repeat two additional times with fresh portions of the sample to give a total of 3 observations. Contact CPC Quality Services, Technical Service or Product Development immediately if any abnormalities are observed.

The test sample is to be compared to a standard, they are evaluated and a subjective comparison made. Evaluation of the test sample may be reported as "normal" or "abnormal". With some products, standard descriptive evaluations may be used to report relative degrees of variation, i.e., lighter, darker, etc. Some products also use standard photographs or charts to illustrate grading scales. Refer to the product specification.

Test Method

Company:

- ☐ *Personal Products Worldwide*
☐ *Personal Products Company*
☐ *Desbiens Products Inc.*

- ☐ *Johnson & Johnson Products Inc.*
☐ *Odonto Corporation Ltd.*
☒ *Johnson & Johnson Consumer Products Co.*

Document No.: TM7252

Franchise:

Location: ALL APPLICABLE

Document Type: Permanent

Expiration Date: None

Subject: VISUAL

12.3 APPEARANCE OF NON-FORMULATED PRODUCTS

The sample must be examined carefully, to ensure that the specified characteristics conform to established definitions, and if required, compare to a standard as indicated in the specification.

12.4 WORKMANSHIP

The packaging must be clean. Check for scuffs, dents, or any malfunction. Examine the labelling for centering, screening damage, looseness, etc. Check for leakage and the presence and integrity of seals. Determine the accuracy of codes and expiration date, if applicable. If folding carton is present, it must be compatible with the container. Check the functionality of the container and/or package - it should perform in its intended manner.

12.5 CERTIFICATE OF ANALYSIS

If a certificate of analysis or similar document is a condition of release or acceptance, examine the document to confirm that the appropriate tests were performed and that the suppliers results meet the specification.

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7716

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

CONFIDENTIAL

Subject: LECO CARBON DETERMINATOR FOR USE IN INSOL & MAGNESITE ($MgCO_3$) % DETERMINATION

REVISION	AUTHORIZATION	DESCRIPTION OF CHANGE
12/02/88	BCR011164	New Test method.
08/21/95	CR020688	Location revised. (Spec. Dept.)

Test Method

Company:

☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7716

Franchise:

Location: ROYSTON, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: LECO CARBON DETERMINATOR FOR USE IN INSOL & MAGNESITE ($MgCO_3$) % DETERMINATION

1.0 SCOPE & PURPOSE

This method is designed to rapidly determine the carbonates in talc.

2.0 UNUSUAL SAFETY PRECAUTIONS

Crucibles get very hot. Handle crucibles with tongs only. Do not drop. Keep a fire extinguisher nearby and know how to use it.

3.0 PRINCIPLES OF METHOD

The Leco EC-12 determines carbon content. In principle, the sample is combusted with oxygen in the induction furnace using copper accelerator. Approximately 97% of the carbon is oxidized to CO_2 , and about 3% combusts to CO which is catalytically converted to CO_2 . During combustion, the concentration of gases in the closed loop rapidly becomes homogeneous. Only CO_2 is detected in the chamber. The solid state detector is an energy detector. A filter is used to pass the appropriate IR wave length to the detector. In the absence of CO_2 , the energy received by the detector is maximum. During combustion, the IR absorption properties of CO_2 in the chamber causes a loss of energy; therefore, a loss in signal results, which is proportional to the concentration of the gas. This proportional change is electrically processed to be displayed as percent carbon.

4.0 FUNDAMENTAL EQUATIONS



5.0 INTERFERENCES

Water any moisture in the sample will also absorb IR radiation and affect the reading.

6.0 PRECISION & ACCURACY

Duplicate determinations should not vary by more than 0.01% carbon for 66 talc.

7.0 ANALYSIS TIME

Man Hours (hr.)

Overall Time (hr.)

First Sample

0.1

0.1

Each Additional Sample

0.07

0.07

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

Document No.: TM7716**Franchise:****Location:** ROYSTON, KOLMAR**Document Type:** Permanent**Expiration Date:** None**Subject:** LECO CARBON DETERMINATOR FOR USE IN INSOL & MAGNESITE ($MgCO_3$) % DETERMINATION**8.0** APPARATUS

- 8.1 Leco EC-12 Carbon Determinator
- 8.2 Electronic Balance
- 8.3 Ceramic Crucibles
- 8.4 Glass Scoop
- 8.5 Calculator

9.0 REAGENTS

- 9.1 Iron Chip Accelerator
- 9.2 Copper Accelerator

10.0 STANDARDIZATION

The following is the necessary routine maintenance and calibration of the Leco Carbon Determinator Model EC-12. This procedure is to be done according to the following schedule:

ONCE PER DAY

- Step 1. Replace glass wool in dust trap with 3 one inch pieces, packed loosely.
- Step 2. Replace anhydron tube with freshly packed tube. Pack new tube with a small plug of glass wool, fresh anhydron, and another plug of glass wool. Be sure there is a screen in the top of the tube and a micron filter in the bottom of the tube. (Insert micron filter with screw provided).
- Step 3. Brush out combustion tube. If tube is severely pitted or there is a large amount of slag build-up, replace tube.
- Step 4. Calibrate using the following procedure:
 - A. Turn function selector knob to the "Calibrate" position.
 - B. Run a calibration ring with known value with a scoop of copper accelerator in crucible.
 - C. When the read light comes on, adjust the calibrate dial until the DVM indicates the value of the calibration standard.
 - D. Record the calibrate dial reading.
 - E. Repeat Steps b through d four more times.
 - F. Determine the average calibrate dial reading by adding all five of the readings together and dividing by five.

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G. Set the calibrate dial to the average dial reading determined above.

H. Return the function selector knob to the "Operate" position.

Step 5. Inspect all "0" rings for burns, contamination and cuts. Replace if necessary.

ONCE PER WEEK

Step 1. Replace ascarite tube with freshly packed tube. Pack new tube with a small plug of glass wool, fresh ascarite and another plug of glass wool. Be sure there is a screen at both ends of the tube. Mark the date on the side of the tube with lab marker.

Step 2. Replace the cellulose tube when half of the cellulose turns black. Pack new tube loosely, but filled with fresh cellulose.

EVERY SIX MONTHS

Step 1. Remove the furnace front panel and check all screws and nuts for tightness on both the power supply and the oscillator chassis.

11.0 SAMPLE PREPARATION

Remove all moisture from sample.

12.0 PROCEDURE

Step 1. Be sure function knob has been returned to the operate setting.

Step 2. Turn on the Gas/Pump and the furnace power switches. (The main power switch remains on at all times to maintain unit temperature.)

Step 3. Set the Automatic/Manual switch to Automatic.

Step 4. At this point, be sure that the furnace is closed so that the unit can purge any residuals that may be in the lines. Purging is complete when the red "read" light comes on.

Step 5. Put a crucible on the balance, cover with windscreen and tare.

Step 6. Remove windscreen and place 0.200 grams of sample into the crucible.

Step 7. Replace windscreen and record sample weight.

Step 8. Compact the sample by tapping the crucible on the counter top.

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Step 9. Place one scoop each of copper and iron accelerators in crucible.

Step 10. Open the furnace and place the crucible on the pedestal, then close the furnace. The analyze cycle will begin when the furnace is closed.

Step 11. When the "read" light glows red, record the value displayed on the DVM readout.

13.0 CALCULATIONS

$$C = \frac{R}{W}$$

Where: C = Percent Carbon
 R = Digital Readout
 W = Sample Weight

To determine percent $MgCO_3$ or percent insoluble material, refer to the following chart. A factor is given for interpolating between percent carbon values.

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LECO CARBON DETERMINATOR

INSOLS & $MgCO_3$ FOR WINDSOR TALC

<u>% Carbon</u>	<u>$MgCO_3$</u>	<u>Insol</u>
.01	.27	99.21
.02	.31	99.15
.03	.34	99.09
.04	.38	99.02
.05	.41	98.96
.06	.44	98.90
.07	.48	98.83
.08	.51	98.77
.09	.55	98.71
.10	.58	98.64
.11	.62	98.58
.12	.65	98.52
.13	.68	98.45
.14	.72	98.39
.15	.75	98.33
.16	.79	98.26
.17	.82	98.20
.18	.86	98.14
.19	.89	98.07
.20	.93	98.01
.21	.96	97.95
.22	.99	97.88
.23	1.03	97.82
.24	1.06	97.76
.25	1.10	97.69
.26	1.13	97.63
.27	1.17	97.57
.28	1.20	97.50

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Subject: ATOMIC ABSORPTION SPECTROPHOTOMETRY IN DETERMINING ARSENIC CONTENT IN TALC

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
12/02/88	BCR011166	New Test method.
08/21/95	CR020688	Location revised. (Spec. Dept.)

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Expiration Date: None

Subject: ATOMIC ABSORPTION SPECTROPHOTOMETRY IN DETERMINING ARSENIC CONTENT IN TALC

1.0 SCOPE & PURPOSE

This method is for the determination of trace arsenic in talc products. Determination is by atomic absorption spectrophotometry.

2.0 UNUSUAL SAFETY PRECAUTIONS

Apparatus uses high voltages. It should not be operated with covers removed. High intensity light is emitted from the heated graphite tube. Do not look directly at the graphite tube during operation to avoid possible injury to the eyes. Wear safety glasses. Graphite tube reaches extreme temperatures.

3.0 PRINCIPLE OF METHOD

The "ground state" atom absorbs light energy of a specific wave length as it enters the "excited state". As the number of atoms in the light path increases, the amount of light absorbed also increases. By measuring the amount of light absorbed, a quantitative determination of the amount of analyte can be made. The use of special light sources and careful selection of wavelengths allow the specific determination of individual elements. (Analytical Methods for Atomic Absorption Spectrophotometry, 1982, p. 1.2)

4.0 FUNDAMENTAL EQUATIONS

Not Applicable

5.0 INTERFERENCES

Many interferences are common and most can be recognized and dealt with. The use of nickel nitrate as a matrix modifier coupled with the proper furnace program should adequately deal with this analysis. Refer to analytical methods manuals for details.

6.0 PRECISION AND ACCURACY

Precision will be ± 0.1 ppm. for first order dilutions
Precision will be ± 1.0 ppm. for second order dilutions

****Note:** First order dilution is standard extract (1:10) or (1:20)
Second order dilution: Any additional dilution up to a total of (1:200).

7.0 <u>ANALYSIS TIME</u>	<u>Man Hours (hr.)</u>	<u>Overall Time (hr.)</u>
Each Sample	1.6	1.8
Each Additional Sample	0.2	0.2

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8.0 APPARATUS

Perkin-Elmer Model 1100 Atomic Absorption Spectrophotometry with Model HGA 400 Graphite Furnace and Model AS40 Autosampler. Beakers, volumetric flasks, a hot plate, funnels, filter paper, and stirring rods are needed for the acid extract procedure.

9.0 REAGENTS

Arsenic Reference Stock Solution-Certified Atomic Absorption Standard, Fisher No. SO-A-449. Several arsenic standard solutions will be made from this standard, at various concentrations.

Nickel Nitrate Matrix Modifier-Certified Nickel Nitrate Crystals, Fisher No. N-62. Dissolve 1.2 g. nickel nitrate crystals in 100 ml. of distilled water.

Hydrochloric Acid, 12.1 Normal, Diluted to 2 Normal-Dilute 166 ml. concentrate to 1 liter with distilled water; 0.5 normal-dilute 41 ml concentrate to 1 liter with distilled water.

10.0 STANDARDIZATION

Refer to 12.B and 12.C for standardization procedures.

11.0 SAMPLE PREPARATION

11.1 Weigh 10.00 +/-0.01g of sample into a 250 ml. beaker.

11.2 Add 50 ml. of 0.5 N HCl and bring to a boil on a hot plate.

11.3 Boil gently for 15 minutes, taking care that the mixture does not foam excessively. Stir the mixture intermittently with a glass stirring rod to return sample to the liquid phase.

11.4 Cool the mixture and allow it to settle.

11.5 Decant the supernatant liquid through a filter paper into a 100 ml. (or 200 ml.) volumetric flask, retaining as much of the insoluble material in the beaker as possible. Add 10 ml. of hot purified water to the beaker, stir, let settle, and decant again.

11.6 Repeat the washing two more times.

11.7 Wash the filter paper with 10 to 15 ml. of hot purified water into the flask. Cool the flask to room temperature and fill to the mark with purified water and mix.

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12.0 PROCEDURE

12.1 Turning on Instrument:

- Step 1. Turn on voltage conditioner.
- Step 2. With EDL power supply in continuous mode, with igniter on and in place, turn power on and adjust dial to "high power" setting. Then immediately adjust wattage to 8, and allow to warm up for five minutes.
- Step 3. Swing the HCL Lamp into position and turn on the AA.
- Step 4. Allow AA to finish initialization step. Upon successful completion of initialization, in element select mode, select furnace mode. Enter date, then go to program mode.
- Step 5. Set technique to AA-BG, integration time to 5.0s, read delay to 0s, plot scale to Auto, calibration to auto, set concentrations to ul/g, enter standards 77.0, 230, and 460, and set reslope value to 230. Go to setup mode. Swing the EDL Lamp into position, then switch it to external modulation. Adjust the wattage to 8.
- Step 6. Allow warm-up time of 20 minutes.
- Step 7. During warm-up turn on argon, cooling water, furnace, and autosampler. Run furnace at 50 degrees for 20 seconds to purge room air. Enter furnace program. Calibrate temperature control assembly to 2300 degrees. Run several blank cycles. Sample carousel can be loaded at this time.
- Step 8. Adjust the wattage to the recommended EDL Lamp setting.

FURNACE PROGRAM

Drying Step 1:	90 temp/1 ramp/30 hold
Charring Step 2:	1300 temp/20 ramp/30 hold
Cooldown Step 3:	20 temp/1 ramp/5 hold
Atomization Step 4:	2300 temp/0 ramp/5 hold, read, stop flow
Cleanout Step 5:	2650 temp/1 ramp/5 hold
Cooldown Step 6:	20 temp/1 ramp/ 5 hold

** NOTE: Drying, atomization, and charring temperatures may be adjusted as needed.

For samples with 1/100 or greater dilutions, alter the program as follows. This will help narrow and normalize the absorption curve. Calibrations must be done with the altered program. Some sensitivity will be lost.

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Charring Step 2: 1350 temp/20 ramp/30 hold
 Atomization Step 4: 2400 temp/0 ramp/5 hold

12.2 Standardization (Calibration):

- Step 1. In set up mode, set gain. Determine adequate stability.
- Step 2. In continuous mode, set autozero. Determine adequate stability.
- Step 3. Program autosampler for 10 ul sample volume and 10 ul alternate volume.
- Step 4. Go to run mode. Run sample blank until absorbance units read zero or less. Press autozero soft key.
- Step 5. Run 77.0 ppb. standard twice. Press standard #1 soft key.
- Step 6. Repeat Step 5 for 230 ppb. and 460 ppb. standards.
- Step 7. Continue running standards until reproducibility is satisfactory.
- Step 8. Calibration can also be done automatically using the autosampler program.

12.3 Standards:

Arsenic standards will be made as follows:

- a. Each month a secondary standard will be made up from the primary stock solution (1000 ppm). The concentration of the secondary standard shall be 10 ppm and be made by diluting 5.00 ml. of primary stock to 500 ml. with 100 ml. 2N HCl and distilled water.
- b. The calibration standards shall be made up daily from the secondary standard. Their concentrations shall be 77.0 ppb, 230.0 ppb, and 460.0 ppb. They shall be made up by diluting the following quantities of secondary standard to 100 ml. with 25 ml of 2N HCl and distilled water.

77.0 ppb standard:	.77 ml. of 100 ppm dil. to 100 ml
230.0 ppb standard:	2.30 ml. of 10 ppm dil. to 100 ml
460.0 ppb standard:	4.60 ml. of 10 ppm dil. to 100 ml

****NOTE:** Only class A glassware will be used and appropriate pipetting methods to optimize precision.

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12.4 Operation:

- a. Enter last sample number and number of replicates on autosampler.
- b. In program mode, enter corresponding number of replicates and desired printer parameters.
- c. Enter first sample number, and turn on printer using print key and printer on/off key on autosampler.
- d. Move autosampler to first sample using manual key.
- e. Start running sequence using start/stop key on autosampler.
- f. Check periodically to be sure sampler is working and sample is drying.
- g. After last sample is finished, check data and do additional dilutions on individual samples, as necessary. Re-run these samples manually.
- h. It is wise to start with a 1/100 dilution on extracts that are potentially greater than 10 ppm. Running a sample with excessively high arsenic content will produce an undesirable "memory" which will persist through the next few samples.

****NOTE:** Both calibration and the following sample testes can be set up in a single program on the autosampler. Set number of standards, last sample number, start at autozero position, initiate with start/stop key.

13.0 CALCULATIONS AND CONCLUSIONS

Answers for arsenic content will be given in parts per million. The AA readout is in parts per billion. For a sample with a 1:10 dilution, i.e. 10 grams of sample powder extracted with 100 ml. of acid/water (standard extract), divide the ppb answer by 1000, then multiply by 10 (dilution factor). You must carefully keep track of any other dilutions or changes in sample size so that you multiply by the proper dilution factor each time.

Atomic Absorption Spectrophotometry Correlation Data With Existing Test Method 7169 In Determining Arsenic Content In Talc.

Test Method

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Subject: ATOMIC ABSORPTION SPECTROPHOTOMETRY IN DETERMINING ARSENIC CONTENT IN TALC

Sample population is from silo composite samples

<u>Date</u>	<u>TM7169 (ppm)</u>	<u>A.A. (ppm)</u>	<u>Difference (TM - AA)</u>
03/21/88	0.3	0.3	0.0
03/21/88	0.3	0.2	0.1
03/23/88	0.6	0.3	0.3
03/23/88	0.2	0.3	-0.1
03/28/88	0.4	0.4	0.0
03/28/88	0.4	0.4	0.0
04/05/88	0.6	0.4	0.2
04/05/88	0.5	0.4	0.1
04/11/88	0.6	0.5	0.1
04/11/88	0.8	0.5	0.3
04/16/88	0.9	0.7	0.2
04/16/88	0.9	0.7	0.2
04/20/88	0.3	0.3	0.0
04/20/88	0.5	0.4	0.1
04/25/88	0.3	0.4	-0.1
04/25/88	0.4	0.4	0.0
04/28/88	0.5	0.4	0.1
05/10/88	0.5	0.4	0.1
05/13/88	0.8	0.7	0.1
05/20/88	0.8	0.6	0.2
06/01/88	1.1	0.8	0.3
06/27/88	1.4	1.2	0.2
07/05/88	2.0	1.8	0.2
07/27/88	1.7	1.8	-0.1
09/14/88	1.0	0.9	0.1
09/27/88	1.2	1.2	0.0
09/28/88	1.2	1.0	0.2
10/06/88	0.7	0.8	-0.1
10/20/88	0.3	0.4	-0.1
<hr/>			
Average	0.73	0.64	
Variance	0.19	0.17	
Std. Dev.	0.44	0.41	
Minimum	0.20	0.20	
Maximum	2.00	1.80	

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Document No.: TM7807**Franchise:****Location:** ROYSTON, SILLIKER (NJ),
SKILLMAN, KOLMAR**Document Type:** Permanent**Expiration Date:** None**CONFIDENTIAL****Subject:** MICROBIAL EVALUATION OF RAW MATERIAL TALC AND RAW CORNSTARCH

<u>REVISION</u>	<u>AUTHORIZATION</u>	<u>DESCRIPTION OF CHANGE</u>
08/12/88	BCR010944	Test method updated.
07/13/95	CR021637	Location revised. Product page deleted. Specification completely revised. (See back-up for specifics). (D. O'Rourke) (908-874-1482)
08/20/96	CR025166	Sec. 11.2, renumbered last paragraph as 12.0. Sec. 12.0, changed the word "same" to "original", Secs. 12.1, 12.2 and 12.3 added. (D. O'Rourke) (908-874-1482)
05/12/97	CR027531	Added note to Section 7.4.2 for talc silo samples. (C. Wilkes) (706-245-2101)
07/15/97	CR028245	Changed company name throughout document. Sec. 5.10, changed to read, "Incubators: 30-35°C and 20-25°C." Sec. 10.2, updated mL amount from "0.5mL" to "2.5mL". Sec. 10.3, changed last sentence "< 5" to "< 1". (L. Wojnarowicz) (908-874-1309)

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Document No.: TM7807

Franchise:

Location: ROYSTON, SILLIKER (NJ),
SKILLMAN, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: MICROBIAL EVALUATION OF RAW MATERIAL TALC AND RAW CORNSTARCH

1.0 SCOPE & PURPOSE

This method is applicable to the determination of microbial populations in raw material talc and raw corn starch used in making JOHNSON'S Baby Powder, Shower to Shower, JOHNSON'S Baby Medicated Powder, JOHNSON'S Medicated Powder, STS Medicated Powder, and Micatin Powder.

2.0 UNUSUAL SAFETY PRECAUTIONS

None.

3.0 PRINCIPLE OF METHOD

Method is based on transferring aliquots of product to specific nutrient media, incubating the test under optimal temperatures, then examining for presence of microbial growth.

4.0 INTERFERENCES

- 4.1 Determine sterility and growth-supporting properties of media according to QAP44001 or equivalent.
- 4.2 Conduct environmental control monitoring of the test area (QAP04004 or equivalent).
- 4.3 As a sterility check, pour one plate from each flask of agar used.

5.0 APPARATUS

Standard Bacteriological Laboratory Equipment and Supplies:

- 5.1 Large Petri Dishes (150 x 15 mm)
5.2 Small Petri Dishes (100 x 15 mm)
5.3 Screw Cap Bottle
5.4 Pipettes
5.5 Colony Counter
5.6 Anaerobic Jar
5.7 Spatula
5.8 Balance
5.9 Orbital Shaker set at 180 to 200 RPM (optional)
5.10 Incubators: 30–35°C and 20–25°C

6.0 CULTURE MEDIA & REAGENTS

- 6.1 Sabouraud Dextrose Agar (SDA) or Low pH Mycophil Agar (LMA)

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Subject: MICROBIAL EVALUATION OF RAW MATERIAL TALC AND RAW CORNSTARCH

- 6.2 Lethen Agar with 0.0025% Triphenyl Tetrazolium Chloride (TTC)
- 6.3 Anaerobic Agar (AA)
- 6.4 Lethen Broth, 90 mL and 40 mL
- 6.5 Fluid Thioglycollate Medium, 190 mL
- 6.6 Diagnostic Agars as required
- 6.7 Clostrisel Agar
- 6.8 Gas Pak — anaerobic system and anaerobic indicator

7.0 PHASE I PROCEDURE

- 7.1 Weigh approximately equal aliquots of product from each sample to total 10 grams into a sterile screw capped bottle containing 40 ml of Lethen Broth to obtain the 1/5 suspension. Shake the bottle 50 times through a distance of one foot. Test immediately after shaking and prior to settling.

7.2 Plating Procedure for Aerobic Bacteria

- 7.2.1 For Large Plates — Immediately withdraw 2.5 ml aliquots of the 1/5 suspension and transfer to each of 2 petri dishes.

or

- 7.2.2 For Small Plates — Immediately withdraw 1.0 ml aliquots of the 1/5 suspension and transfer to each of 5 petri dishes.

- 7.2.3 Add Lethen Agar with TTC, mix the contents well by swirling and allow to set.

7.3 Plating Procedure for Fungi

- 7.3.1 For Large Plates — Immediately withdraw 2.5 ml aliquots of the 1/5 suspension and transfer to each of 2 petri dishes.

or

- 7.3.2 For Small Plates — Immediately withdraw 1.0 ml aliquots of the 1/5 suspension and transfer to each of 5 petri dishes.

- 7.3.3 Add LMA or SDA, mix the contents well by swirling and allow to set.

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7.4 Enrichment for Diagnostic Tests

7.4.1 Aerobic Microorganisms (bagged material) — Transfer 5 mL from the 1/5 suspension prepared in Sec. 7.1 into 90 ml of Lethen Broth, shake to mix well.

7.4.2 Aerobic Microorganisms (bulk material) — Transfer 1 gram of product into 90 ml of Lethen Broth, shake to mix well.

NOTE: For talc silo samples transfer 10 grams of product into 90 ml of Lethen Broth, shake to mix well.

7.4.3 Clostridium species (bulk material)

7.4.3.1 Aseptically transfer 2.5 ml of the 1/5 suspension into each of 2 petri dishes.

7.4.3.2 Add AA, mix well by swirling and allow to set.

7.4.4 Clostridium species (bagged material)

7.4.4.1 Aseptically transfer 10 gram talc to 190 mL FTM.

7.4.4.2 Shake 50 times through a distance of one foot to mix well.

8.0 INCUBATION

8.1 Aerobic Bacteria

Incubate all plates prepared in 7.2 at 30–35°C for a minimum of 48 hours to a maximum of 5 days (48 hours optimum).

8.2 Fungi

Incubate all plates prepared in 7.3 at 20–25°C for a minimum of 5 days to a maximum of 10 days (5 days optimum).

8.3 Diagnostic Tests

8.3.1 Incubate the Lethen Broth referred in 7.4.1 or 7.4.2 at 30–35°C for a minimum of 48 hours to a maximum of 5 days (48 hours optimum) or 24 hours on an Orbital shaker set at 180 to 200 RPM.

8.3.2 Incubate the AA prepared in 7.4.3 under anaerobic conditions at 30–35°C for a minimum of 48 hours to a maximum of 5 days (48 hours optimum).

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Location: ROYSTON, SILLIKER (NJ),
 SKILLMAN, KOLMAR

Document Type: Permanent

Expiration Date: None

Subject: MICROBIAL EVALUATION OF RAW MATERIAL TALC AND RAW CORNSTARCH

8.3.3 Incubate the FTM prepared in 7.4.4 under anaerobic conditions at 30–35°C for a minimum of 48 hours to a maximum of 5 days (48 hours optimum).

9.0 OBSERVATIONS

- 9.1 Examine all the plates and count the colonies observed as described in TM7846.
- 9.2 Shake the enrichment broth from 8.3.1 thoroughly and streak one drop from 1.0 ml pipette onto the diagnostic agars specified in TM7814, Sections 7.1 through 7.6. Examine the media for growth and gram stain according to TM7816.
- 9.3 Examine the AA plates from 8.3.2 for the presence of growth. If growth is observed, note number of colonies and test each colony according to TM7814, Sec. 7.6.
- 9.4 Shake the anaerobic enrichment from 8.3.3 thoroughly and streak from a 1.0 mL pipette onto Clostrisel Agar, as specified in TM7814, Sec. 7.6.

10.0 CALCULATIONS

- 10.1 Count the colonies on each plate and record.
- 10.2 Each 2.5 mL aliquot of the 1:5 product dilution yields 0.5 grams product per plate. Each 1.0 mL aliquot of the 1:5 product dilution yields 0.2 grams of product per plate. To determine CFU/gram of product, add the counts from the two 2.5 mL aliquot platings (or the five 1.0 mL aliquot platings) of the bacterial plates. Repeat as above, if mold is present on LMA plates. To achieve total count, add the bacterial and fungal counts together.
- 10.3 Example:

Amount Plated From 1:10 Dilution	Bact. CFU	Bact. Count/Gm	Mold CFU	Mold Count/Gm	Total/Gm
2.5 mL	3		1		
2.5 mL	2	5	2	3	8
1.0 mL	0		0		
1.0 mL	1		0		
1.0 mL	1	3	1	2	5
1.0 mL	1		1		
1.0 mL	0		0		

If no colonies are observed, report as < 1 CFU per gram.

Test Method

Company:

- ☐ Personal Products Worldwide
☐ Personal Products Company
☐ Desbiens Products Inc.

- ☐ Johnson & Johnson Products Inc.
☐ Odonto Corporation Ltd.
☒ Johnson & Johnson Consumer Products Co.

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11.0 CONCLUSIONS

- 11.1 Compliance with the product specification is achieved if the total count is within the specified limits and there are no harmful microorganisms detected.
- 11.2 If the total count is above the limits of the raw material specification, or if the raw material is found to contain a harmful microorganism, a Phase II procedure must be conducted to validate the original result.

12.0 PHASE II PROCEDURE

Test the original sample(s) using 2 1/2 times the original amount of product tested, performing only the relevant section of the test procedure which did not meet the specification.

12.1 Diagnostic Enrichment

Aseptically transfer 25 grams of the raw material into 100 mL Lethen Broth. Shake well and transfer 12.5 mL into 225 mL Lethen Broth. Incubate as indicated in Sec. 8.3.1. Streak on the appropriate diagnostic agars applicable to the harmful microorganism(s) found in the Phase I test. (If the Phase II Diagnostics test does not meet the specification, report that the product is not acceptable and conduct an investigation.)

12.2 Total Count

Aseptically transfer 25 grams of the raw material into 100 mL Lethen Broth. Shake well. Perform plating procedure as described in Sec. 7.2 and incubate as described in Sec. 8.2 for aerobic bacteria. Perform plating procedure as described in Sec. 7.3 and incubate as described in Sec. 8.3 for fungi. (If the Phase II Total Count test does not meet the specification, report that the product is not acceptable and conduct an investigation.)

12.3 Clostridium species

12.3.1 Bulk Material

Aseptically transfer 25 grams of the raw material into 100 mL Lethen Broth. Shake well. Perform plating procedure as described in Sec. 7.4.3 and incubate as described in Sec. 8.3.2. (If the Phase II Clostridium test does not meet the specification, report that the product is not acceptable and conduct an investigation.)

12.3.2 Bagged Material

Perform Sec. 7.4.4 in triplicate and incubate as described in Sec. 8.3.3. (If the Phase II Clostridium test does not meet the specification, report that the product is not acceptable and conduct an investigation.)

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ANNEX BPRODUCT PRICE; ANNUAL ADJUSTMENT

A. Initial Price For Products

GRADE 66 TALC US\$360 PER METRIC TON

FOB LUDLOW, VERMONT BULK RAIL

SUBJECT TO ESCALATION/DEESCALATION INDEXED TO PPI AS DETAILED
IN SECTION 1 (B)

B. Annual Price Adjustment

The following calculation illustrates the annual adjustment to be made to the price paid by Buyer for Products hereunder. For illustration purposes only, the calculation is made as if the annual price adjustment were effective April 15, 2001 in respect of the Contract Year beginning on that date. Thus, the illustration uses data for the years 2000 and 2001. The data required to make this illustration, *i.e.* the Producer Price Index for Nonmetallic Mineral Products, Minerals and earths ground or treated, Series ID PCU3295#1 (the "Index"), published by the United States Department of Labor, Bureau of Labor Statistics (the "BLS") on its website on April 23, 2001, is attached to this Annex B. For actual calculations, data published by the BLS on its website for the second week of April shall be used.

1. *Assume for purposes on illustration only that the price paid prior to April 15, 2001 was \$400 per metric ton.*
2. *The average of the final data for January, February and March of the year prior to the Contract Year just ended is determined as follows:*

January, 2000	129.5
February, 2000	130.7
March, 2000	130.8
Average:	(129.5 + 130.7 + 130.8)/3 = 130.3

3. *The average of the final or preliminary data for January, February and March of the Contract Year just ended is determined as follows:*

January, 2001	131.4
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February, 2001	134.1
March, 2001	134.0
Average:	$(131.4 + 134.1 + 134.0)/3 = 133.2$

4. *The percentage change in the price for Products payable during the next Contract Year is determined as follows:*

The difference in the two averages determined above is $133.2 - 130.3 = 2.9$.

The percentage change in the Index between relevant years is $2.9/130.3 = 0.022$, or 2.2%.

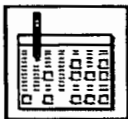
5. *The new price to be paid by the Buyer for the Contract Year beginning April 15, 2001, is determined as follows:*

The new price to be paid is $\$400 \times (1.000 + 0.022) = \408.80 .

If the percentage change in the Index between relevant years had been negative (-2.2%) the new price to be paid would have been $\$400 \times (1.000 - 0.022) = \391.20 .

Series Id: PCU3295#1 Industry: Minerals and earths ground or treated Product: Minerals and earths, ground or treated Base Date: 8506													
Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Ann Avg
1991	112.8	112.2	112.2	113.3	112.9	111.5	112.3	113.0	112.2	112.2	111.6	112.3	112.4
1992	112.3	112.2	112.3	112.6	112.6	113.4	112.9	113.3	113.3	113.6	112.6	112.3	112.8
1993	114.5	113.9	113.5	113.4	115.4	115.4	115.4	115.3	115.7	115.3	115.4	115.4	114.9
1994	115.5	116.5	116.5	117.4	117.8	117.2	117.5	117.4	117.5	117.2	117.1	117.1	117.1
1995	117.7	119.5	119.5	119.6	119.6	119.6	120.2	120.2	120.3	120.4	120.4	120.4	119.8
1996	120.9	122.5	122.5	123.8	123.7	123.9	123.9	123.3	123.3	123.6	123.6	123.7	123.2
1997	124.5	125.8	125.8	126.5	126.5	126.5	126.4	126.4	126.4	126.7	126.7	126.7	126.2
1998	126.8	127.2	127.2	127.3	127.6	127.7	127.7	127.7	127.6	127.6	128.0	128.0	127.5
1999	128.0	128.6	128.6	129.2	129.3	129.3	129.7	129.7	129.7	129.7	129.1	129.1	129.2
2000	129.5	130.7	130.8	130.8	130.9	130.7	130.9	130.6	130.7	130.7	131.2	131.2(P)	130.7(P)
2001	131.4(P)	134.1(P)	134.0(P)										

P : Preliminary. All indexes are subject to revision four months after original publication.



Producer Price Indexes Home Page

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<http://146.142.4.24/servlet/SurveyOutputServlet?jrunsessionid=988032148518101304>

4/23/2001

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ANNEX C

INSURANCE COVERAGE

Seller will obtain and maintain the following insurance coverage:

- Commercial general liability coverage in the amount of US\$5 million
- Product liability insurance in the amount of US\$5 million per occurrence, US\$10 million aggregate

Such policies shall name Buyer as an additional insured and shall provide for 30 calendar days written notice of cancellation. Seller shall annually provide Buyer with a certificate of insurance evidencing required coverage.